

BEFORE THE HONORABLE EDWARD M. CHEN

FOOD & WATER WATCH, INC., et al,)
)
)
 Plaintiffs,)
)
 vs.) No. C 17-2162 EMC
)
 U.S. ENVIRONMENTAL PROTECTION)
 AGENCY, et al,)
) San Francisco, California
 Defendants.) Tuesday
) June 16, 2020
) 1:30 p.m.

TRANSCRIPT OF REMOTE ZOOM BENCH TRIAL PROCEEDINGS

APPEARANCES :

For Plaintiffs: WATERS KRAUS & PAUL
222 North Pacific Coast Highway
Suite 1900
El Segundo, California 90245
BY: MICHAEL P. CONNETT, ESQ.
CHARLES ANDREW WATERS, ESQ.

WATERS & KRAUS LLP
3141 Hood Street
Suite 700
Dallas, Texas 75219
By: KAY GUNDERSON REEVES, ESQ.

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

Reported By: *Debra L. Pas, CSR 11916, RPR, RMR, CRR*
Official Reporter - US District Court
Computerized Transcription By Eclipse

Debra L. Pas, CSR, RPR, RMR, CRR
Official Reporter - U.S. District Court - San Francisco
(415) 431-1477

APPEARANCES: (CONTINUED)

For Plaintiffs: NIDEL AND NACE, PLLC
 5335 Wisconsin Avenue, NW
 Suite 440
 Washington, DC 20015
BY: CHRISTOPHER THOMAS NIDEL, ESQ.

For Defendants: U.S. DEPARTMENT OF JUSTICE
 Environmental Defense Section
 601 D Street, NW
 Room 8814
 Washington, DC 20004
BY: DEBRA J. CARFORA, ESQ.

U.S. DEPARTMENT OF JUSTICE
 Environment & Natural Resources Div.
 P.O. Box 7611
 Washington, DC 20044
BY: BRANDON N. ADKINS. ESQ.
SIMI BHAT, ESQ.
JOHN THOMAS H. DO, ESQ.

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PROCEEDINGS

P R O C E E D I N G S

JUNE 16, 2020

1:31 P.M.

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THE CLERK: Court is now in session. The Honorable Edward M. Chen is presiding.

Calling Civil Action 17-2162, Food & Water Watch versus Environmental Protection Agency.

Counsel, please state your appearances for the record beginning with plaintiff's counsel.

MR. WATERS: Andy Waters for the plaintiffs.

THE COURT: All right. Good afternoon, Mr. Waters.

MR. WATERS: Good morning judge -- or afternoon, yes.

THE COURT: Yes, afternoon.

MR. CONNETT: Good afternoon, Your Honor. Michael contaminant for the plaintiffs.

THE COURT: All right. Thank you, Mr. Connett.

MS. REEVES: Good afternoon, Your Honor. It's Kay Reeves for the plaintiffs.

THE COURT: Hello, Ms. Reeves.

MR. NIDEL: Good afternoon, Your Honor. Chris Nidel for the plaintiffs.

THE COURT: All right. Good afternoon, Mr. Nidel.

MS. CARFORA: Good afternoon, Your Honor. Debra Carfora for EPA.

THE COURT: Hello, Ms. Carfora.

PROCEEDINGS

1 **MR. ADKINS:** Good afternoon, Your Honor. Brandon
2 Adkins for EPA.

3 **THE COURT:** All right. Thank you, Mr. Adkins.

4 **MS. BHAT:** Good afternoon, Your Honor. Simi Bhat for
5 EPA.

6 **THE COURT:** All right. Good afternoon, Ms. Bhat.

7 **MR. DO:** And John Do for EPA, good afternoon.

8 **THE COURT:** Good afternoon, Mr. Do.

9 Okay. We are in the process of further cross of
10 Dr. Chang; right?

11 **MR. CONNETT:** Yes, Your Honor.

12 In light of the stipulation that was just filed to
13 withdraw Dr. Chang's testimony on the Spanish abstract,
14 plaintiffs have no further cross-examination at this time.

15 **THE COURT:** All right.

16 All right. Then any redirect?

17 **MS. BHAT:** Yes, Your Honor. There is a brief
18 redirect.

19 **THE COURT:** All right. If we could call Dr. Chang
20 back.

21 **THE CLERK:** I am promoting Dr. Chang into the virtual
22 well.

23 **THE COURT:** Good afternoon, Dr. Chang. Welcome.

24 **THE WITNESS:** Good afternoon. Thank you.

25 **THE COURT:** We're going to resume with the

CHANG - REDIRECT / BHAT

1 government's redirect.

2 MS. BHAT: Thank you, your Honor.

3 ELLEN CHANG,

4 called as a witness for the Defendant herein, having been
5 previously sworn, resumed the stand and testified further as
6 follows:

7 REDIRECT EXAMINATION

8 BY MS. BHAT

9 Q. Dr. Chang, have you ever provided an opinion to a client
10 that was adverse to the client's interests?

11 A. Yes, several times.

12 Q. Can you please elaborate?

13 A. Sure. So in some cases -- I can't go into too many
14 details, but sort of generally, you know, I was asked to do a
15 literature review on a given topic, sometimes in the context of
16 litigation. And then I came back with, you know, a scientific
17 opinion that was not favorable to, I think, their case. And
18 then in those cases -- in some of those cases, actually, you
19 know, the client said thank you and we didn't proceed any
20 further.

21 In a couple of the case, my initial opinion was sort of,
22 you know, counter to their position, and so something that I
23 appreciated was that they continued working with me, but we
24 just changed the scope of what I was working on. So, you know,
25 I didn't address the part --

1 (Court reporter clarification due to audio
2 interference.)

3 **A.** I don't remember exactly what I said. We changed the
4 scope and then continued working on a different scope.

5 **Q.** Thank you.

6 I believe that opposing counsel asked you about a
7 systematic review on dioxin. Do you recall that?

8 **A.** Yes. I published three.

9 **Q.** And in -- were any of your -- can you describe the
10 relation between -- the causal conclusion in that systematic
11 review with the conclusion of the International Agency for
12 Research on Cancer?

13 **A.** I yes. So the International Agency for Research on Cancer
14 has classified 1378, you know, tetrachlorodibenzo. I don't
15 know exactly what it is, but it's TCDD. It's a certain dioxin.
16 It has classified it has a Group 1 human carcinogen for certain
17 types of cancer, in particular for lung cancer.

18 Our review pertained to lymphoid malignancies, prostate
19 cancer and diabetes, which is not addressed by the
20 International Agency for Research on Cancer. And that agency
21 has not concluded that dioxin causes malignancies or prostate
22 cancer. So our conclusion is consistent with that of IARC.

23 I think another thing actually that I didn't mention
24 yesterday, I sort of wanted to mention, is in the table of
25 systematic reviews where the funding agencies were listed, all

1 of those have been disclosed.

2 So, you know, when we publish the papers, the declaration
3 of interest was published along with the paper, including the
4 funding source.

5 **Q.** I believe opposing counsel also asked you about glyphosate
6 and your causal conclusion on glyphosate and
7 lymphohematopoietic cancers. My apologies for butchering that.

8 Was that conclusion also consistent with the conclusion of
9 the International Agency for Research on Cancer?

10 **A.** Yes. So IARC has classified glyphosate as a Group 2A
11 probable human carcinogen, as Mr. Connett and I discussed
12 yesterday.

13 In particular, they have classified it in that category
14 based on sufficient evidence of carcinogenicity in animals, but
15 I think they -- they call it limited evidence in humans, and
16 our review pertained to humans in particular. And we agreed
17 with IARC that the -- the evidence humans is limited.

18 **Q.** I believe that you also a conclusion, a causal conclusion
19 regarding perfluorinated chemicals.

20 Was that also consistent with the conclusion of the
21 International Agency for Research on Cancer and the Health
22 Council of the Netherlands?

23 **A.** Yes. We published a review in 2016 of perfluorinated
24 chemicals, in particular, PFOA, and PFOS. The -- IARC
25 evaluated the potential human carcinogenicity of PFOA and

1 classified it was a Group 2B possible human carcinogen based on
2 limited evidence, I believe, in both animals and in humans.
3 And that is consistent with our findings.

4 And then the Health Council of the Netherlands, I think
5 in -- the IARC review, I believe, was in 2016. The Health
6 Council of the Netherlands review, I think, was a little bit
7 before that, and they -- they classified it I think as Group 3
8 human carcinogen, which means that there was insufficient
9 evidence to determine its potential carcinogenicity. That was
10 for PFOA.

11 Q. And, Doctor, are you aware of any contemporaneous
12 conclusions from independent health agencies that disagree with
13 your causal conclusion in your systematic reviews?

14 MR. CONNETT: Overbroad.

15 THE COURT: Overruled.

16 A. I'm not aware of any, any disagreement from health or
17 regulatory agencies.

18 BY MS. BHAT

19 Q. Now, you were speaking yesterday with opposing counsel
20 about the methodological rigor of the Mexico City and Canadian
21 cohort studies.

22 I wanted to ask you, you know, given your agreement about
23 their methodological rigor, why are those Mexico City and
24 Canadian cohort studies not sufficient to conclude that
25 community water fluoridation in the United States causes

1 neurodevelopmental toxicity?

2 **A.** Sure. I think, you know, Dr. Hu mentioned this to some
3 extent. As he said, no observational epidemiological study is
4 perfect. Every such study has some limitations.

5 So, for instance, as Dr. Hu mentioned, measuring urinary
6 fluoride during pregnancy in a -- I think they collected the
7 second void of the morning. It's not ideal. It's not a
8 fasting first morning urine. It's not a 24-hour urine. Those
9 are better for measuring fluctuating biomarkers, but on the
10 other hand it's a trade-off. So if they had tried to collect
11 first morning or 24-hour urine, they would have had probably
12 lower participation, which could lead to selection bias.

13 So there is this trade-off between, you know, a better,
14 more precise, more accurate exposure and potential selection
15 bias for non-participation.

16 You know, likewise, in the Canadian study they collected
17 spot urine. So -- so urine at any time of the day, which is --
18 you know, it's convenient. It's doable, feasible. It's also,
19 you know, not -- not ideal.

20 Likewise, each study controlled for a range of confounders
21 or potential confounders. They collected a lot of information,
22 but the reality is that, you know, no epidemiological study can
23 control for all confounders.

24 And so another issue is that even when you collect data on
25 potential confounders, the way in which you collect the data or

1 the way in which you classify it in a statistical analysis can
2 result in residual confounding.

3 So, for instance, one of the studies -- I can't -- one of
4 them classified maternal smoking as, I think, current, former
5 or never. And so that may be insufficient to capture the
6 effect of smoking on neurodevelopmental outcomes.

7 Also, classifying education. I think the Mexico City
8 study might have classified maternal education as high school
9 and below or above high school. That kind of classification,
10 again, is relatively crude and it may not fully capture, you
11 know, confounding by maternal education or socioeconomic
12 status.

13 So, you know, with two studies that are relatively
14 rigorous and then the other studies, the other four studies I
15 mentioned that are, I think -- they don't rise to the level of
16 the Mexico City and the Canadian cohort studies, but they are
17 still informative studies. Those other four did not find
18 significant associations.

19 I think with the two prospective birth cohort studies that
20 did find adverse associations, you know, there is some
21 inconsistency. I think it's not enough to -- to reach a
22 conclusion that neurodevelopmental harm is caused by fluoride
23 exposure at .7 milligrams per liter.

24 You know, even a couple more studies, a couple more
25 prospective cohort studies would contribute substantially more

1 evidence on this topic. I think it's too sparse right now.

2 **THE COURT:** Can I ask a question?

3 You mentioned lack of precision, for instance, in the
4 collection of urine. And I heard testimony about adjusting for
5 creatinine and specific gravity.

6 Is there any reason to suspect or believe that, let's say,
7 fasting first morning void or 24-hour collection versus spot
8 would tend to increase or decrease any association found?

9 We've heard the general rule that imprecision tends
10 towards the null. Is there something about the collection of
11 urine that you saw that would exaggerate the association?

12 **THE WITNESS:** There is no information that I saw that
13 can address whether it would exaggerate or underestimate the
14 association.

15 So I think, as I mentioned yesterday, you know, bias in an
16 estimate due to exposure error, measurement error gets pretty
17 complicated when you have a continuous exposure, one that goes
18 from zero up to any level. You know, it's not a yes/no
19 exposure, which is what we've with urinary fluoride.

20 And then we have also a continuous health outcome. And
21 then we have a lot of potential confounders.

22 So unless, you know, we have a yes/no, exposure and it's
23 classified with error that's completely random, then the
24 resulting effect on the association can go either up or down.

25 And so let me -- let me try to think of an example. So

1 let's say -- I mean, this is just sort of a general example.

2 Let's say women who are -- mothers who were working, you
3 know, employed, actively employed during their pregnancy had to
4 go to work early, so they tended to give first morning urine.
5 Whereas, mothers who were not working because they are
6 unemployed during their pregnancy provided it later in the day.
7 Then the mothers who were working would have a more accurate
8 and more precise measurement of fluoride in their urine.

9 And then, let's say, mother's employment is also related
10 to neurodevelopmental outcomes.

11 That could result in -- in a bias in the estimate toward,
12 you know -- you know, it could -- it could exaggerate an
13 association if the -- the more error prone measurement in the
14 mothers who are not working leads to, you know, an adverse
15 association in that group. Whereas, the mothers who are better
16 educated and are working, you know, if there's a better
17 neurological -- better neurodevelopmental outcome in that
18 group, you could get bias, you know, toward an over estimated
19 association. But without data, it's hard to evaluate that type
20 of scenario.

21 **THE COURT:** But you didn't see anything that
22 suggested that here. You don't have enough information one way
23 or the other with respect to this study?

24 **THE WITNESS:** Unfortunately, no. I think we don't
25 know to what degree exposure is mismeasured. Because if we

1 did, we would correct it.

2 And so we don't know how much error is present, you know,
3 in the measured level compared to what it truly should be.

4 **THE COURT:** What about the fact that two different
5 studies use two different methods of collection as you mention.
6 One was second void and the other was spot; correct? Is that
7 what you said?

8 **THE WITNESS:** That's correct.

9 **THE COURT:** Okay. So even given the two different
10 methodologies in collection, an association was found -- some
11 association was found in each. Is that -- does that tell you
12 anything?

13 **THE WITNESS:** Not necessarily. I think a lot of the
14 potential errors in both of the studies are subtle. And so I
15 don't see, for instance, one glaring problem that was present
16 in one versus the other or, you know, some -- one glaring
17 problem that affects both of them.

18 But I think, you know, both of the studies had some
19 measurement error inevitably in the exposure. They may have
20 had some selection bias because they both had to exclude many
21 subjects who did not provide sufficient data.

22 As I mentioned, every observational epidemiologic study
23 has some confounding. And so I think it's too hard to say, you
24 know, whether the -- the presence of a statistically
25 significant association in both studies is due to real causal

1 consistency or similar biases between the two or chance.

2 **THE COURT:** So let's take selection bias for a
3 moment. You gave an example insufficient data. They didn't
4 get enough samples or whatever it was, and they are obviously
5 excluded from the study; correct?

6 **THE WITNESS:** They are either excluded from the
7 entire study or they didn't provide enough data for this
8 particular analysis, but they -- you know, they could be
9 included in a study of different health outcomes, for instance.

10 **THE COURT:** All right. So the same question: Is
11 there anything that you saw that would give reason to suspect
12 or believe that that selection would have been biased either
13 toward or away from the null?

14 **THE WITNESS:** As I remember, I don't think that the
15 published studies provided data on the women who were in the
16 cohorts, but didn't contribute enough data to be included in
17 the analyses. So I don't think I saw anything in the
18 publications that would provide information on potential
19 selection bias.

20 **THE COURT:** You can't tell one way or the other given
21 the limited data?

22 **THE WITNESS:** Yeah.

23 **THE COURT:** And another example, education.
24 Bifurcating the education decision, I forget whether that was
25 done in these studies or not, as just between a more -- high

1 school or above or no high school.

2 Any reason *a priori* to believe that that tended to bias --
3 that uncertainty tended to lead to exaggeration or
4 underestimating.

5 **THE WITNESS:** I would say it's pretty theoretical
6 which direction it would go in.

7 I think it would likely lead to some residual confounding,
8 because there is still a lot of granularity, I would say, in
9 education that is missed by that classification.

10 But how it affects the estimates, you know, given the web
11 of variables that are related to each other, I think it's hard
12 to say.

13 I mean, you know, I guess when we think about smoking, for
14 instance, and lung cancer. If we classify it as ever versus
15 never smoking, that's a very crude classification; right? But
16 we will see a difference between ever smokers and never
17 smokers. But whether that is overestimated or underestimated
18 compared with, you know, if with really classify ever smoking
19 carefully into packs, you know, cigarettes a day, duration of
20 smoking, age at starting to smoke, age at stopping smoking, the
21 time since last smoking, I think it's hard to say.

22 **THE COURT:** Well, there is some errors, like, failure
23 to take into account the litter effects in animals, and there's
24 other ones. You can kind of see which way that's going to go.

25 Did you see anything in the Mexico or Canada study that

1 jumped out at you as to, you know, factors -- potentially
2 confounding factors that were not taken into account or
3 measurement imprecisions that were done that would lead you to
4 think, with reason, that was going to exaggerate, lead to an
5 exaggeration of the association?

6 **THE WITNESS:** I would say it's too speculative on my
7 part without the raw data, for instance, to estimate how
8 certain variables would be related to fluoride exposure and how
9 they would be related -- I mean, how they would be related to
10 neurodevelopment we probably know from our studies.

11 So, for example, maternal education or maternal IQ, for
12 instance. Higher IQ in the mother is related to, you know,
13 better neurological, neurodevelopmental outcomes in the child.

14 But how that might be related to urinary fluoride level or
15 error in measurement of urinary fluoride, I -- I don't know.

16 **THE COURT:** All right. So to determine the
17 confounding effect you would need to know some of the
18 additional pieces of information?

19 **THE WITNESS:** Correct. You need to know the
20 direction of association with both the exposure and the
21 outcome. And potentially with -- with modifiers, if are there
22 any.

23 **THE COURT:** All right. Thank you.

24 **THE WITNESS:** You're welcome.

25 **MS. BHAT:** And, Your Honor, I just have one last

1 question.

2 **BY MS. BHAT**

3 **Q.** Dr. Chang, were you aware of any decisions by an
4 independent health agency finding causation based on two
5 observational epidemiology studies?

6 **MR. CONNETT:** Overbroad.

7 **THE COURT:** Yeah. Why don't you be a little more
8 precise? That seems -- maybe you can ask -- can you rephrase
9 that? Let me listen to it again.

10 **MS. BHAT:** Yes. I will try.

11 **BY MS. BHAT**

12 **Q.** Dr. Chang, given two observational epidemiological
13 studies, such as the American Element Cohort Studies, are you
14 aware of any decisions by an independent health agency finding
15 causation based on two such observational epidemiological
16 studies?

17 **MR. CONNETT:** Your Honor, I'm going to object again,
18 both on being overbroad and an incomplete hypothetical.

19 **THE COURT:** Yeah. I don't think there is enough
20 there. Obviously, the answer may depend on the quality of
21 those studies.

22 So I think that hypothetical is not helpful. It's -- it
23 is overbroad.

24 **MS. BHAT:** Can I ask it with -- regardless of
25 quality? Would that make it less...

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1 **THE COURT:** Well, I'm not sure how helpful that
2 answer. I guess. If the answer is: Has there ever been a
3 finding -- and you use the word "causation" as opposed to "risk
4 assessment." So you are intending to use the word "causation"
5 there?

6 **MS. BHAT:** Yes. I'm intending to use the word
7 "causation."

8 **THE COURT:** The question is whether any agency has
9 ever found causation based on nothing more than two studies,
10 epidemiological studies? That excludes animal studies and
11 other extrapolations, or what's...

12 **MS. BHAT:** Yes, yes, excluding animal studies.

13 **THE COURT:** So just based on two epidemiological
14 studies, regardless of how well those were conducted?

15 **MS. BHAT:** Yes, that's the question.

16 **THE COURT:** Okay. That's a precise question. Go
17 ahead.

18 **THE WITNESS:** Can I answer that, your Honor?

19 **THE COURT:** Yes.

20 **THE WITNESS:** I'm not aware of any.

21 **MS. BHAT:** Okay. Thank you, Your Honor. No further
22 questions at this time.

23 **THE COURT:** Okay. Thank you.
24 Anything on recross?

25 **MR. CONNETT:** No, Your Honor.

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1 **THE COURT:** All right. Thank you, Dr. Chang. Thank
2 you for your time. Thank you for coming back for a second day.
3 Appreciate it.

4 **THE WITNESS:** Thank you, Your Honor. It's an honor.
5 (Witness excused.)

6 **THE COURT:** Okay. So we will proceed to next
7 witness, government's next witness.

8 **MS. CARFORA:** Yes, Your Honor. Thank you. EPA calls
9 Dr. Tala Henry.

10 **THE COURT:** That's right. I meant the -- you have
11 another witness after this; is that right?

12 **MS. CARFORA:** We have one deposition to play. It's
13 about six minutes, your Honor.

14 **THE COURT:** Okay. All right. Thank you.

15 **THE CLERK:** All right. I'll promote what I think is
16 Dr. Henry into the well.

17 **THE COURT:** All right. I think we can see you Dr.
18 Henry.

19 **THE WITNESS:** All right.

20 **THE COURT:** Thank you.

21 All right, Angie. Administer the oath.

22 **TALA HENRY,**
23 called as a witness for the Defendant, having been duly sworn,
24 testified as follows:

25 **THE WITNESS:** I do.

1 **THE CLERK:** Thank you.

2 **DIRECT EXAMINATION**

3 **BY MS. CARFORA**

4 **Q.** Good afternoon, Dr. Henry. Can you please state your name
5 for the record.

6 **A.** Tala Henry.

7 **Q.** And can you state the name of your employer?

8 **A.** The U.S. Environmental Protection Agency.

9 **Q.** And, Dr. Henry, how long have you worked at EPA?

10 **A.** Over 25 years.

11 **Q.** What's your highest level of education?

12 **A.** I have a PhD in pharmacology from the University of
13 Minnesota.

14 **Q.** Dr. Henry, what is your current position at EPA?

15 **A.** I am the deputy office director of the Office of Pollution
16 Prevention and Toxics. Also called OPPT, I'm sure, henceforth.
17 And OPPT's primary mission is to administer the Toxic
18 Substances Control Act, which is called TSCA, and the Pollution
19 Prevention Act, among other things.

20 **Q.** Dr. Henry, have you held any other positions at EPA?

21 **A.** Yes, several. Prior to becoming the deputy office
22 director, I was the director of the Risk Assessment Division
23 within OPPT. And prior to that I was the director of the
24 National Program Chemicals Division, which does more risk
25 assessment activities. That division is also in OPPT. And I

1 have been a staff toxicologist in a number of other program
2 offices across EPA.

3 Q. And I see here from your C.V. that you were a member of
4 EPA's Risk Assessment Forum from 2009 to 2017. Can you explain
5 for the Court what that was?

6 A. Sure the Risk Assessment Forum is a standing committee of
7 senior science experts at EPA who convene to address complex or
8 challenging science issues related to risk assessment, and to
9 promote adoption of these consensus approaches through
10 agency-wide guidance.

11 Q. Now, is that a committee that you have to be appointed the
12 to?

13 A. Yes. You're nominated by your program office, and then
14 your selection is made on your experience and your underlying
15 scientific credentials by the Risk Assessment Forum steering
16 committee and three other senior EPA managers.

17 Q. And how does the Risk Assessment Forum communicate its
18 findings within or outside the agency?

19 A. I think probably the number one most known way, a forum
20 product, if you will, are the various guidelines for different
21 kinds of toxicity risk assessments, such as the Guidelines for
22 Neurotoxicity Risk Assessment. There is one for cancer and
23 reproduction and development and so forth.

24 In addition, sometimes there are technical white papers
25 that are published on particular topics related to risk

1 assessment and the methods to conduct it.

2 Also, the Risk Assessment Forum often convenes expert
3 workshops and publishes out proceedings and recommendations
4 from those.

5 Q. I note from your C.V., Dr. Henry, that you've written
6 articles in the area of assessing the relevance for studies for
7 regulatory decision-making; is that correct?

8 A. That's correct. Most recently I was on the steering
9 committee and a participant in the Society of Environmental
10 Toxicology and Chemistry workshop that was on that very topic.
11 It's increasing the utility of toxicology data for regulatory
12 decision-making. There were a number of papers published, and
13 I was coauthor on two of them.

14 Q. I also noticed from your C.V. that you also published
15 papers on risk assessment; is that correct?

16 A. I've published several papers on the data and methods that
17 are used in risk assessments, by certain types of data or
18 models.

19 Q. Dr. Henry, it's true that -- have you been involved in
20 risk assessments at EPA?

21 A. Yes, indeed.

22 Q. And how many years would you estimate to have been
23 involved in -- in risk assessment in the regulatory context?

24 A. As I mentioned, I have been with EPA for about 25 years.
25 I would say 21 of those I have been conducting one or another

1 type of risk assessment in a variety of program office. The
2 other four I spent as a, you know, laboratory research
3 scientist in the Office of Research and Development.

4 Q. And if you had to estimate, how many risk assessments do
5 you think you have been involved with in EPA?

6 A. All together, I don't have an exact count, but it has to
7 be hundreds. And they -- a wide variety of different types,
8 ranging from site specific risk assessments for cleanups at
9 RCRA and Superfund sites, to during my tenure in the Office of
10 Water I developed ambient water quality criteria for human
11 health and aquatic life under the Clean Water Act. These are
12 water quality criteria, but it's a form of a risk assessment.
13 And then finally in OPPT I have been conducting a variety of
14 types of risk assessments under TSCA.

15 Q. Can you just very quickly explain, when you say a variety
16 type of risk assessments under TSCA, what do you mean by that?

17 A. Okay. So in the TSCA world there are sort of -- we divide
18 our chemical universe into new chemicals. Those are chemicals
19 that have not yet been commercialized, and then existing
20 chemicals are those that are already out there in the world of
21 commerce.

22 So I have been involved in conducting these new chemical
23 risk assessments, which have to be, according to statute,
24 completed within 90 days. So you can well imagine -- and there
25 are no data requirements for companies to submit a

1 pre-manufacture notice to do that. So you can well imagine
2 that we're using different types of methods and models and so
3 forth for that type assessment.

4 Also, while I was the director of the Risk Assessment
5 Division, we conducted some, what I'll call limited scope risk
6 assessments prior to TSCA being amended. And by "limited
7 scope" I mean they were focused on one or a few conditions of
8 use.

9 And then when TSCA was amended in 2016, starting then, we
10 have been conducting much more comprehensive risk assessments.
11 And by "comprehensive" I mean generally assessing many, many
12 more uses.

13 **Q.** Now, you noted that you have been involved in management
14 for many years at EPA. I'm wondering, of the hundreds of risk
15 assessments you may have been involved with, how many of those
16 do you think or could you estimate that you participated in the
17 primary scientific work?

18 **A.** Again, I don't think I can without going back and tallying
19 it up.

20 But obviously when I was a staff scientist, I was involved
21 in the -- you know, the actual technical work. But certainly
22 as my position changed to one of a science manager, it evolved
23 into more of, you know, guiding and directing the approaches
24 taken to a risk assessment.

25 And, of course, so as both division director of the Risk

1 Assessment Division and the deputy office director, I provide
2 technical oversight and policy oversight to the ongoing risk
3 assessments now.

4 Q. Can you tell us real quick what do you mean by a
5 "technical oversight"?

6 A. Oh, I have been there since, you know, being a
7 toxicologist, as well as having been involved for a long time
8 in risk assessment. When I read these risk assessments, I'm
9 looking to see that appropriate methods are applied; that there
10 is clarity and completeness to the data considered and the
11 analyses conducted.

12 But then as far as sort a more policy review, which I also
13 need to do, is I'm looking for concordance of the assessment
14 with the established EPA risk assessment practices and
15 guidelines, as well as any science policy that might go along
16 with those, either at the agency level or the OPPT level.

17 Q. Now, Dr. Henry, other than your risk assessment, your
18 experience with the Risk Assessment Forum, have you
19 participated in developing risk assessment principles outside
20 of EPA?

21 A. Yes. I think probably the most notable example is my
22 involvement for over ten years, at least, in the Organization
23 for Economic Cooperation and Development, the OECD, Chemical
24 Safety Program. So within that realm.

25 I have been involved primarily, but not exclusively, in

1 the working party for hazard assessment, and I've actually
2 chaired that group for the last four years. What that group
3 does, often in collaboration with the working party on exposure
4 assessment, is we develop various tools and models and
5 approaches for conducting risk assessments.

6 And we also have a cross-over at times with the test
7 guideline program that was brought up yesterday relative to the
8 testing scheme that was used in some study or another.

9 But it's these OECD test guidelines is also part of the
10 OECD chemical safety program. And it's 37 countries
11 internationally that come together to try to find consensus on
12 approaches to conducting testing, toxicity testing, and how to
13 apply that in risk assessment.

14 **Q.** Now, other than the Risk Assessment Forum, which I think
15 you testified to it covers kind of risk assessment policy for
16 the agency as a whole, have you had other experience
17 participating or developing risk assessment principles within
18 EPA programs?

19 **A.** Well, certainly most recently there is the TSCA. So I was
20 involved in development of the risk evaluation rule and, of
21 course, implementing the amendments to TSCA since 2016.

22 **Q.** Now, in your work implementing amended TSCA, what is your
23 understanding of whether risk assessment is an actual
24 requirement under the statute?

25 **A.** Well, Section -- my understanding is Section 6A, which is

1 the section of TSCA that provides the authority to take
2 regulatory action, to omit or otherwise limit, and five other
3 options under there.

4 Before you can do that, you need to have an unreasonable
5 risk determination. And this whole new section of TSCA,
6 Section 64, is all about conducting risk evaluations on
7 existing chemicals as the foundational basis for getting to
8 whether or not that unreasonable risk is there, and if so, to
9 direct you to Section 6A to conduct a risk assessment.

10 Q. Now, you mentioned the risk evaluation rule. Can you very
11 quickly tell us what that is?

12 A. Congress directed -- in part of the statute to the
13 amendments, directed EPA to establish the processes and
14 procedures for conducting these risk evaluations by rule. And
15 so -- and they also instructed us to do this within one year of
16 enactment, which in our world of rulemaking is quite an
17 miracle. But we did, in fact, propose, take public comment and
18 finalize that rule on the one-year anniversary of the TSCA
19 amendments being passed.

20 Q. Dr. Henry, if I refer to that as the risk evaluation rule,
21 is that okay with you?

22 A. That would be perfect. That's what I call it.

23 Q. Great. Now, Dr. Henry, we're talking about risk
24 assessment and -- and under TSCA you were talking about risk
25 evaluation. So I want to ask you: Is there a difference

1 between risk assessment and risk evaluation?

2 **A.** Yes. So risk assessment, we heard some words about that,
3 but just to refresh memory, including my own. Back in 1983 the
4 National Research Council of the National Academies of Sciences
5 established what we refer to in the risk assessment realm, the
6 risk assessment paradigm. They outlined these four steps that
7 constitute a risk assessment: The hazard identification, the
8 dose response analysis and exposure assessment, and then you
9 integrate those two pieces into a risk characterization. So
10 that's a risk assessment.

11 What TSCA added on top of that is this unreasonable risk
12 finding. So they -- TSCA adds the risk determination. So
13 simply put, a risk evaluation under TSCA is a risk assessment,
14 plus a risk determination.

15 **Q.** Dr. Henry, what was your assignment for this litigation?

16 **A.** I was to act as an expert resource on risk assessment
17 generally, risk assessment as conducted under TSCA and, also,
18 just provide information about how we've gone about
19 implementing the 2016 amendments to TSCA.

20 **Q.** And how did you go about completing your assignment?

21 **A.** Well, specifically relative to this case, typically what
22 would happen is I would receive an expert plaintiff report. I
23 would read through that. In doing so identify if there were
24 areas or parts of it that I needed to consult with other EPA,
25 my staff or other experts.

1 Sometimes, time permitting, I might go and find some of
2 the underlying cited articles. Upon completing that, and if I
3 consulted with someone else, then I would formulate my summary
4 of opinions.

5 Q. Would you say that this was consistent with how you review
6 scientific products offered to you in your capacity as deputy
7 director of programs within OPPT?

8 A. Yes, similarly. Although this one was a much -- these
9 reports were far more limited than what we typically do under
10 TSCA.

11 Q. Now in your review -- did you review Dr. Thiessen's expert
12 report?

13 A. Yes. I think there were three -- two.

14 Q. In your review of Dr. Thiessen's expert reports, did you
15 rely on the expertise of individuals within your program
16 office?

17 A. A couple of people to a limited extent, yes.

18 Q. And can you explain for us why?

19 A. Well, so our office has a senior science advisor, you
20 know, for the whole office. And then, of course, my old
21 division, the Risk Assessment Division, has lots of different
22 scientific experts that are toxicologists, epidemiologists,
23 exposure science experts, et cetera.

24 So, you know, just typically the way I work is to go
25 through something, contemplate to myself if I think I can

1 address it or if I need, you know, somebody that adds a little
2 deeper understanding on one of the particular issues or
3 modeling or something. And then just as a general matter, I
4 tend to like to have another senior scientist, so to
5 corroborate or review my work or my thinking.

6 Q. In other words, the people that you relied on in forming
7 your opinions, are those people that you would generally rely
8 on in performing your everyday duties?

9 A. Yes, yes. Absolutely.

10 Q. Do you need to pick up a pen, Doctor?

11 A. I dropped something.

12 Q. Did you review Dr. Grandjean's expert report?

13 A. Yes. There were two, as I recall.

14 Q. And in your review of Dr. Grandjean's expert reports, did
15 you rely on the expertise of individuals within your program
16 office?

17 A. Yes. Quite similar, as I described. Again, if there was
18 an area that I thought somebody might have a deeper knowledge,
19 I might consult with them. And then, of course, I do like to
20 have someone else review my work.

21 Q. Now, Dr. Henry, before we get into your opinion, I'm going
22 to ask you a few questions about the terminology and concepts I
23 think that you're going to be using in your testimony today.

24 So can you tell us, what is the -- or what is your
25 understanding of the risk standard applied by TSCA?

1 A. It's whether or not an unreasonable risk is presented
2 under the conditions of use.

3 Q. Now, is unreasonable risk defined by the statute?

4 A. No, it is not.

5 Q. And did EPA codify a definition of unreasonable risk?

6 A. No, we -- we did not. And we did -- when we proposed the
7 risk evaluation rule, we solicited comment on whether or not we
8 should. And overwhelmingly, people felt we probably should
9 not, having not implemented or run the process thus far.

10 Nonetheless, we did include into the rule some things that
11 we would likely consider making, moving from the risk
12 assessment into the risk evaluation. Things to consider in
13 making the unreasonable finding.

14 Q. And can you -- off the top of your head, can you tell us
15 what some of those factors might be?

16 A. We'll see. Certainly, of course, you know, filing the
17 risk assessment paradigm and the things that you consider in a
18 risk assessment, we would consider the hazards of the chemical.

19 We would also consider, you know, the nature and magnitude
20 and that sort of thing of the exposure.

21 Certainly, the population that we assess or to which risk
22 may or may not be posed. And specifically including
23 susceptible subpopulations, as required by TSCA.

24 Also, the severity of the hazard. So there's -- you know,
25 there's things that present extreme hazards, such as, even

1 death. And certain -- and then other hazards that are nowhere
2 near as severe and might be reversible and things like that.

3 And then finally, of course, you have to always consider
4 uncertainties associated with the overall assessment, but also
5 each of the pieces that I just described.

6 Q. Now, is that an exclusive list of factors that OPPT might
7 consider in making an unreasonable risk determination?

8 A. No, not necessarily. We were -- we were clear that this
9 was a -- these are some of the things, but not necessarily
10 limited to.

11 Again, it just kind of goes to the fact that you can't
12 predict for any given chemical all the various things that
13 would come up.

14 So under TSCA, you know, we have to move on and do these
15 assessments. Every chemical has inherently different
16 characteristics and toxicities. But also every chemical thus
17 far in our experience, I think we're up to about 23 now that
18 we're working on, has different underlying datasets. It has
19 different amounts and types of toxicity data. It has different
20 amounts and types of exposure data and so forth.

21 So we didn't think that, you know, we could say for sure
22 today written down that this is the only thing we'll ever
23 consider. We did not.

24 Q. I know you discussed already the difference between risk
25 assessment and risk evaluation. But other than this specific

1 components of the risk evaluation process, are you aware in
2 your experience of any other requirements for reaching a risk
3 determination under TSCA as it's amended?

4 **A.** Yes. So TSCA Section 26 indicates that EPA, in making any
5 decision based on science, needs to ensure that it's the best
6 available science.

7 And furthermore, in making decisions we need to use a
8 weight of the scientific evidence.

9 **Q.** Now, in your experience implementing TSCA, are you aware
10 if TSCA defined either of those terms, "weight of the
11 scientific evidence" or "best available science" in the
12 statute?

13 **A.** Not specifically.

14 **Q.** Well, can you explain just in very simple terms what is
15 meant by "best available science"?

16 **A.** When EPA wrote the risk evaluation rule, we defined it --
17 or EPA defined it as science which is reliable and unbiased.
18 And then the statute spoke to several considerations that we
19 should take in determining that, and so those were also
20 included in the risk evaluation rule as well.

21 **Q.** Dr. Henry, have you read the MIREC cohort study, the Green
22 2019 study that we have been talking about this past week or
23 so?

24 **A.** I have read the journal article.

25 **Q.** Have you read the ELEMENT cohort or the Bashash 2017

1 article that we have been talking about?

2 A. I've read the journal article, yes.

3 Q. Dr. Henry, have you listened to all of the testimony over
4 the past six or seven days?

5 A. Yes, I have.

6 Q. In your opinion, are the ELEMENT and MIREC cohort studies,
7 can they be considered the best available science?

8 MR. CONNETT: Foundation, your Honor.

9 THE COURT: Overruled.

10 A. Well, I kind of appreciated listening to all the
11 testimony. These two studies were not part of the original
12 petition, so this was the most in-depth discussion I've heard
13 about them.

14 And basically having listened, I -- I don't think I could
15 answer that question today, because what I heard were a lot of
16 outstanding questions to my mind. And my staff, I'm pretty
17 sure would attest to you, that I always have a lot of
18 questions. So I just felt like there were still a lot of
19 questions, and this kind of goes to this whole uncertainty that
20 we have to consider in making an unreasonable risk finding
21 under TSCA.

22 So I heard, you know, lots of testimony about the sources
23 of fluoride. You know, one cohort has the source being the
24 drinking water. Another has it being salt. Food was talked
25 about and the relative importance of that, or not. I didn't

1 get a really clear, crystal clear understanding about if and
2 how that might be important.

3 But as I think about it in a regulatory context, if I'm
4 being asked to eliminate one particular source of exposure, I
5 think drafting the rule-making, I would be expected to consider
6 the possibility of other sources as well.

7 Because TSCA, just eliminating something, is only one
8 possible choice under the -- under 6A for mitigating risks.
9 There is also the consideration of if you could lower the
10 amount. So is there a place where, you know, one effect versus
11 the other, which is the risk of dental caries comes in.
12 Shouldn't those -- I might have to weigh those among one
13 another.

14 I heard a lot about how people are measuring this
15 exposure. Again, people have been trying to make correlations
16 with the water intake and the urine. And we saw that there is
17 measurements of urine, measurements of plasma or serum. I
18 think one of them even talked about amniotic fluid.

19 So it seems that several of the experts testified that
20 urine is a measure, but is it the best? I -- I would want to
21 have that question further explored, given new studies about
22 the difference between urine and plasma have just come out.

23 We also talked about or heard a lot about timing. And I
24 know that the judge just had a back-and-forth with Dr. Chang
25 about this, but it still seems as though this timing, whether

1 you do it in what trimester and when you -- what time of day
2 and some of that could make a difference. I would want to get
3 my team of experts to help me really understand what those
4 uncertainties are and whether or not they might make these
5 differences.

6 And we talked about -- I heard a lot about correction
7 methods. So you have one cohort correcting -- well, first of
8 all, there is a paper, an earlier paper in the dissertation
9 where there was no correction. And then we found one result.
10 And when we corrected with creatinine, the result changed all
11 together. But it makes me have some questions that are --
12 there must be some uncertainties there.

13 And then the newest study corrected by yet another
14 measure, specific gravity, which was also the correction method
15 used in that very recent University of California study.

16 So I don't -- I'm not at all certain on what's the best
17 method of correction right now.

18 And it seemed to me that the experts themselves might also
19 have these similar questions because I think I heard
20 Dr. Lanphear, if I recollect correctly, that they are indeed
21 going to go back into that Canadian database and try to find
22 data to make further corrections, hopefully, so that maybe we
23 can compare across the cohorts more directly.

24 I think that -- there's a lot of questions in my mind, and
25 I think that they are there because there are still

1 uncertainties around specific aspects of these studies.

2 Again -- well, I can't really answer that here today. I
3 just want to point out that I would never make that
4 determination all by myself. I would do this with, you know, a
5 team of experts who are versed in the risk evaluation that we
6 would conduct, the EPA would conduct under TSCA. So I would
7 have the benefit of this full body of information, and I have
8 the opportunity to ask all these questions and get them
9 clarified.

10 **Q.** Dr. Henry, can you explain what is the term "weight of the
11 scientific evidence" specific to TSCA risk evaluation?

12 **A.** I don't think I can recall the exact notation we put into
13 the rule-making. Just generally speaking, the "weight of the
14 evidence" means the confidence or the inference that you can
15 make from a body of data. It's usually based on -- a lot of
16 EPA guidance is that we need to be comprehensive in identifying
17 it, but it has a lot to do with evaluating its quality and
18 presenting it transparently.

19 **Q.** I'm sorry. I --

20 **A.** Sorry. We did refer in the rule to some words from the
21 Institute of Medicine. We rely on that definition.

22 I think Kris Thayer's testimony may have had that in
23 there.

24 **Q.** Dr. Henry, I apologize. I didn't ask a very good
25 question.

1 My question that I meant to ask you was: Is the term
2 "weight of the scientific," is it specific to TSCA risk
3 evaluations?

4 **A.** Oh, no, no, no. It's well and long established in risk
5 evaluation for sure. I understand it's actually derived from
6 the law. But it's a -- that concept has been pervasive in EPA
7 guidance for a long time.

8 **Q.** Now, is there a specific method that you're aware of for
9 weighing the scientific evidence?

10 **A.** Well, systematic review is a state of the science method
11 that aims to basically increase the rigor and objectivity of
12 conducting a weight of the evidence analysis.

13 **Q.** Now, in your experience implementing amended TSCA, is it
14 your opinion that the systematic review approach is required
15 for regulatory decision-making under Section 6?

16 **A.** In the risk evaluation rule we defined "weight of
17 evidence," and it does include to use a systematic review
18 method for doing all the things I said were included and that
19 Dr. Thayer laid out as part of her analysis of systematic
20 review.

21 **MS. CARFORA:** Your Honor, I'd like permission to put
22 on the screen Trial Exhibit 544. It's a Trial Exhibit. It is
23 in evidence.

24 **THE COURT:** What is it?

25 **MS. CARFORA:** It is the risk evaluation rule.

1 **MR. CONNETT:** No objection.

2 **THE COURT:** Okay. Go ahead.

3 **MS. CARFORA:** Mr. Hambrick, if we can put up
4 Exhibit 544, Page 23, third column middle?

5 (Document displayed)

6 **BY MS. CARFORA**

7 **Q.** Dr. Henry, if you could just read for us the definition of
8 "weight of the scientific evidence" in the risk evaluation
9 rule?

10 **A.** So EPA indicates that:

11 "Weight of the scientific evidence means a
12 systematic review method, applied in a manner suited
13 to the nature of the evidence or decision, that uses a
14 pre-established protocol to comprehensively,
15 objectively, transparently, and consistently identify
16 and evaluate each stream of evidence, including
17 strengths, limitations, and relevance of each study
18 and to integrate evidence as necessary and appropriate
19 based upon strengths, limitations, and relevance."

20 Long winded, I know.

21 **Q.** I was on mute.

22 That term "stream of evidence," can you quickly tell us
23 what that refers to?

24 **A.** So you heard Dr. Thayer on Friday describe it, because
25 her -- as, like, human data, animal data, mechanistic data,

1 cellular data, and that applies in her program because she does
2 hazard assessments. You know, you heard her talk about they do
3 hazard identification and dose response collectively. I call
4 those hazard assessment.

5 But within TSCA, it also applies because in Section 64 it
6 tells us that we have to use a -- the weight of the scientific
7 evidence, not just for hazard, but also to evaluate exposure
8 data.

9 So for us in TSCA, it means the exact same thing as it
10 does in the IRIS program with regard to the hazard data. So it
11 could be evaluated in the human data, the animal data, the kind
12 of cellular, mechanistic data.

13 Also, in our world applies to doing the same thing for
14 exposure data. So exposure data can also vary. It might be
15 measured in air, water, out in the world. It might be modeled
16 based on predictions or certain scenarios in industry or
17 whatever. So we need to do it for both parts, to get to a
18 weight of evidence for both.

19 **MS. CARFORA:** Mr. Hambrick, please clear the screen.

20 (Document removed from display)

21 **BY MS. CARFORA**

22 **Q.** Dr. Henry, does OPPT rely on IRIS systematic review
23 methods for the TSCA risk evaluations?

24 **A.** So, again, we're both using the generalized approach to
25 systematic review, which you heard Dr. Thayer testify that it

1 started out in the clinical medicine realm, and then National
2 Toxicology Program were the leaders in bringing these
3 approaches, the systematic approach, over into evaluating
4 toxicology type information. So we are both using that general
5 framework with the various steps about data collection, data
6 screening, having a predefined question, all those things.

7 The general steps that have been established in the
8 literature and elsewhere, we are using them. But because we're
9 doing it on different types of data in order to fulfill the
10 TSCA requirements for both hazard and exposure, we're doing
11 certain things slightly differently.

12 So, again, the general principles and the framework of
13 steps are the same in both, but in TSCA we make some
14 adjustments.

15 **Q.** So did OPPT develop a systematic review method that's used
16 just for TSCA risk evaluation process?

17 **A.** Yes. In 2018 we published a document. The "Application
18 of Systematic Review in Developing TSCA Risk Evaluations" I
19 think is the title.

20 **Q.** And you said that was in 2018; is that correct?

21 **A.** Yes.

22 **Q.** And is that guidance available? The "Application of
23 Systematic Review in TSCA Risk Evaluations," is that available
24 to the general public?

25 **A.** Yes. We put it out in May of 2018, and we also put out at

1 that very same time the scoped or ten -- the first ten
2 chemicals to be assessed under TSCA. And within those scopes
3 it's basically a demonstration on how we applied that method to
4 ten real risk evaluations.

5 So the scope is essentially that first step that defines
6 the question. But with each and every one of those ten scopes,
7 there were supplemental files that showed our literature search
8 strategy, what criteria that we used to screen things that were
9 relevant on topic versus not, and the resulting full-fledged
10 bibliographies, which were sizeable for some of those
11 chemicals.

12 Q. Now, in a nutshell can you describe, very quickly, how
13 systematic review and weight of the scientific evidence, how
14 those two concepts fit together?

15 A. Sure. For us under TSCA, since the law tells us that we
16 need to base things on best available science and the weight of
17 evidence, OPPT is using systematic review, a state of the
18 science approach, to demonstrate that our risk evaluations and
19 our risk determinations are based on best available science,
20 and that we can roll back that best available science into a
21 rigorous and objective weight of the evidence.

22 Q. Now, you've heard all the testimony this week about the
23 ELEMENT and MIREC cohort studies. Dr. Henry, in your opinion,
24 are these studies enough to understand the full weight of the
25 evidence regarding potential risk to fluoride -- or potential

1 risk from fluoride exposure?

2 **MR. CONNETT:** Objection in terms of vague and
3 ambiguous, and overbroad.

4 **MS. CARFORA:** Let me try to be more specific.

5 **THE COURT:** Rephrase. You say "to understand the
6 full weight of evidence." I'm not sure what that means.

7 **THE WITNESS:** May I take a drink of water?

8 **THE COURT:** Yes.

9 **BY MS. CARFORA**

10 **Q.** Dr. Henry, in your opinion, could you base a risk
11 determination solely on the ELEMENT and MIREC cohort studies?

12 **A.** From everything that I've seen, read and heard, certainly
13 not alone.

14 So we've heard -- you know, we've heard there exists
15 different data streams. So in other words, there's human data
16 about fluoride potential and -- to cause neuro effects. We've
17 also heard there is animal data. So there is that. So,
18 certainly, we could not exclusively do that.

19 First and foremost, I would need my team to go through
20 this -- this systematic way of evaluating the full body. I
21 mean, Dr. Chang pointed out that although -- that there are
22 ten -- at least ten more useful studies. I surely would want
23 my team to look at those, because I think it's agreed by her
24 and some other folks that they can provide insights and
25 potentially -- I mean, I look at it as maybe some of those can

1 help reveal or inform some of these uncertainties that we still
2 have. So, again, you want that whole body of evidence.

3 Certainly, the animal data, because it exists, we need to
4 also probably look at that.

5 And another point that I personally have observed going on
6 here, and I'm not quite sure what to make of it, but this
7 entire petition, as well as this -- this whole case has been
8 looking at just one hazard a potential for neurotoxicity. And
9 that is just not how IRIS assessments, which are hazard
10 assessments only, or TSCA risk evaluation risk assessments are
11 formulated.

12 The first step of hazard identification is to go out and
13 look for all the potential hazards that this chemical might
14 have. I mean, the 2006 NRC report has hazards in different
15 chapters, and we do know there are adverse effects on other
16 organ systems, like, teeth and bones and so forth.

17 So if we were doing this risk assessment at EPA, we would
18 be looking at all of the potential hazards because when you're
19 going to go regulate, you -- we need to know that we're going
20 to regulate in a national regulation. We need to consider all
21 of the hazards, all of the populations. That's how we do it.

22 Q. Dr. Henry, do you recall receiving a petition from the
23 plaintiffs in this case under Section 21 of TSCA?

24 A. Yes. Late in 2016.

25 Q. And what action did the plaintiffs request in the

1 petition?

2 A. I'm paraphrasing, but they asked EPA to exercise our
3 authority under Section 6 to prohibit the meaningful addition
4 of fluoride chemicals, not specifying the exact ones, to U.S.
5 drinking water.

6 Q. And did you participate in forming EPA's response to the
7 plaintiff's Section 21 petition?

8 A. I, along with a team of various scientific and policy
9 experts, drafted the response. Also, our colleagues in the
10 Office of General Counsel were involved as well.

11 Q. Dr. Henry, did you read the petition?

12 A. Yes.

13 Q. When was the last time you read the petition?

14 A. Within the past week, many times.

15 Q. Dr. Henry, do you recall whether the studies cited in the
16 petition all measured the same endpoint?

17 A. Oh, certainly not. I mean, there were human data that
18 measured a variety of different learning and memory and IQ type
19 things. There was animal data that measured lots of different
20 things. There was data -- there was a lot of different kinds
21 of data and measuring different endpoints.

22 Q. Did the petition cite to any studies from Western
23 populations?

24 A. Yes. At that time it mentioned two, the Malen and Till
25 that we've heard a little bit about, which, if I recall, is the

1 one that's looking at ADHD.

2 And then also I cited that Peckham study, which is
3 actually looking at associations with thyroid hormone levels.

4 Q. Dr. Henry, did the petition identify any susceptible
5 subpopulations of concern?

6 A. Yes. They have a list of several that they were asserting
7 were susceptible subpopulations.

8 Q. Do you recall, Dr. Henry, did the petition identify
9 pregnant women as a susceptible subpopulation of concern?

10 A. As I recall, it did not specifically call out that
11 subpopulation.

12 Q. Dr. Henry, would it help you to remember if I showed you
13 the petition -- yes, the petition?

14 A. Yes, yes.

15 MS. CARFORA: Your Honor, permission to put up Trial
16 Exhibit 515, which is an admitted exhibit in this case.

17 THE COURT: Any objection?

18 MR. CONNETT: No objection, your Honor.

19 THE COURT: Go ahead.

20 MS. CARFORA: Mr. Hambrick, if you could put up EPA
21 Trial Exhibit 515, Page 18.

22 (Document displayed)

23 BY MS. CARFORA

24 Q. Dr. Henry, does this help refresh your memory as to
25 whether the petition identified pregnant women as a susceptible

1 subpopulation?

2 **A.** This is not the paragraph.

3 **Q.** All right. It's Page 18.

4 **MS. CARFORA:** I'm sorry, Mr. Hambrick. You're -- I
5 had the PDF page wrong.

6 There we go.

7 (Document displayed.)

8 **BY MS. CARFORA**

9 **Q.** How about this time, Dr. Henry? Does this help your
10 recollection?

11 **A.** Yes. And let me just move around my little panel of
12 pictures here.

13 Yes. It includes infants, the elderly individuals with
14 nutrient deficiencies, kidney disease, and some genetic
15 polymorphisms. But I don't see specifically pregnant women
16 there.

17 **MS. CARFORA:** Can you clear the screen, Mr. Hambrick?
18 (Document removed from display)

19 **BY MS. CARFORA**

20 **Q.** Dr. Henry, do you recall whether the petition also
21 referenced the beneficial health effects of fluoride?

22 **A.** Yes. The plaintiffs -- or the petitioners, sorry, brought
23 a health benefits discussion into their argument around
24 unreasonable risk.

25 **MR. CONNETT:** Your Honor, I'm going to object to this

1 line of inquiry as just irrelevant to the case.

2 **THE COURT:** Well, I mean --

3 **MS. CARFORA:** Your Honor --

4 **THE COURT:** I don't know. I mean, it's in the
5 petition. You can make whatever legal arguments. I'm not sure
6 what we're getting out of this.

7 **MS. CARFORA:** I'll move along, your Honor. I'd just
8 like to make a record on one other issue.

9 **THE COURT:** Okay.

10 **MS. CARFORA:** I'll move along.

11 **BY MS. CARFORA**

12 **Q.** Dr. Henry, did you consider the petition to be a risk
13 assessment?

14 **A.** Not one -- there were missing components and, also,
15 certainly the requirements of TSCA were not met, so no.

16 **Q.** Is it your testimony that any Section 21 petition must be
17 conducted or documented exactly the same way OPPT documents its
18 risk evaluations?

19 **A.** Doesn't need to be documented exactly the same way. But
20 the -- the requisite components, as outlined in TSCA, need to
21 be there. And given that we have only 90 days to respond to a
22 petition, in order for EPA to get to that, to get to that
23 finding of unreasonable risk, one would have to expect that
24 there is a demonstration of that best available science. There
25 needs to be information in some sort of context of how the data

1 presented in support are best available. And then also it
2 needs to be integrated somehow into some semblance of a weight
3 of evidence -- a finding.

4 So, again, I think the fact that TSCA gives us three years
5 to conduct a risk evaluation and only 90 days to respond to a
6 petition, I would interpret that to mean that what comes in as
7 a petition asking for a rule-making under Section 6A needs to
8 for sure have all of the tenets of a TSCA risk evaluation, in
9 their document anyway, that would allow EPA to, in that 90
10 days, make that determination.

11 I think this is also quite consistent with TSCA mandating
12 that EPA follow up and publish within one year of enactment a
13 guidance to assist interested parties to develop a draft risk
14 evaluation.

15 Q. Dr. Henry, did EPA publish guidance to assist interested
16 persons in drafting a risk evaluation?

17 A. Yes. We signed it the very -- one year after enactment.

18 Q. Is that guidance available to the general public?

19 A. Yes, it is.

20 Q. Dr. Henry, what was EPA's response to the petition?

21 A. After carefully consideration, we denied the petition
22 because we did not feel that the petition laid out a reasonable
23 basis to conclude that unreasonable risk was posed by
24 fluoridation chemicals added to drinking water at .7 milligrams
25 per liter.

1 Q. And did you agree with EPA's conclusions?

2 A. Yes, I did.

3 Q. Now, forming your opinions -- well, you already testified
4 that you did review Dr. Thiessen's expert reports consistent
5 with how you review information at EPA; is that right?

6 A. That's right.

7 Q. And in forming your opinions, did you also review
8 Dr. Grandjean's expert reports consistent with how you would
9 review such information at EPA?

10 A. Yes.

11 Q. And in forming your opinions, did you review Dr. Tsuji's
12 expert reports consistent with how you would review such
13 information at EPA?

14 A. Yes. Although they were -- it was a very specific -- it
15 was a different kind of report, but yes.

16 Q. And in forming your opinions, did you review Dr. Chang's
17 expert reports consistent with how you would review information
18 at EPA?

19 A. Yes.

20 Q. And did you ultimately arrive at an opinion regarding the
21 credibility of Dr. Thiessen's conclusions regarding the risk of
22 exposure to fluoridation chemicals?

23 A. Yes. I -- I found -- you want to know what they are?

24 Q. Yes. What did you conclude with respect to
25 Dr. Thiessen's --

1 **A.** I concluded that they just were not -- for various
2 specific reasons, were not a reliable source on which I could
3 make a conclusion of unreasonable --

4 **Q.** And did you -- did you explain the basis for that opinion
5 in your trial declaration?

6 **A.** Yes.

7 **Q.** And did you arrive at an opinion regarding the credibility
8 of Dr. Grandjean's conclusions regarding the risk of exposure
9 to fluoridation chemicals?

10 **A.** Yes. Likewise, I felt that those reports were not a
11 reliable source for a variety of reasons to make a conclusion
12 on.

13 **Q.** And, Dr. Henry, did you explain the basis for your
14 opinions in your trial declaration?

15 **A.** Yes.

16 **Q.** Dr. Henry, I have one last question for you. In your time
17 at -- in your 25 years at EPA and considering your time
18 implementing the TSCA amendments, are you or have you become
19 aware of any reason why United States Environmental Protection
20 Agency would have an interest in denying or hiding a potential
21 risk or hazard from exposure to fluoride?

22 **MR. CONNETT:** Overbroad, and vague and ambiguous.

23 **THE COURT:** Overruled.

24 **A.** No, not to my -- no.

25 **MS. CARFORA:** I have no more questions for this

1 witness.

2 **THE COURT:** All right. Why don't weapon take a break
3 at this point before we resume our cross. Take a 15-minute
4 break.

5 **MR. CONNETT:** Thank you, Your Honor.

6 **MS. CARFORA:** Thank you, Your Honor.

7 **THE CLERK:** Court is in recess.

8 (Whereupon there was a recess in the proceedings
9 from 2:52 p.m. until 3:05 p.m.)

10 **THE CLERK:** Please come to order. Court is now in
11 session.

12 **THE COURT:** Welcome back, everyone.

13 Mr. Connett you have the floor.

14 **MR. CONNETT:** Thank you, Your Honor. Just as a
15 matter of some housekeeping notes, our -- when we raise
16 housekeeping issues, Your Honor, do they count against our
17 time?

18 **THE COURT:** Well, I guess it depends on what it is.

19 **MR. CONNETT:** Because I do want to raise just a few
20 issues, Your Honor, but I also am very mindful that my time is
21 very limited now. So I -- I -- the --

22 **THE COURT:** All right. I won't count it. If it's
23 short, we won't count it. So go ahead and raise your
24 housekeeping issues.

25 **MR. CONNETT:** Thank you, your Honor.

1 The first is I wanted to clarify whether our current time
2 allocation includes the reallocation of deposition time.

3 **THE COURT:** Angie?

4 **THE CLERK:** It does not, your Honor.

5 **THE COURT:** Okay. So then based -- Angie, based on
6 the estimates that we sent last week, I think that would then
7 give us about ten more minutes from what we had, I think, the
8 count from yesterday, which I understand was an hour and ten
9 minutes.

10 The other issue, Your Honor, is we had the evidentiary --
11 the pretrial evidentiary hearing on June 5th, and we had
12 brought to Your Honor's attention our concerns with Dr. Henry's
13 undisclosed BMD opinions. And at that time Your Honor had
14 indicated that in light of the sort of undisclosed nature of
15 those opinions, we would have an extra 30 minutes to explore
16 those opinions.

17 So I want to just clarify if we can do that. I don't
18 expect, Your Honor, that it would be 30 minutes. It may be 15
19 minutes, but I just wanted to get some clarity on that.

20 **THE COURT:** All right. So these are the -- not
21 testified to today, but in the trial declaration, is what
22 you're talking about.

23 **MR. CONNETT:** Correct.

24 **THE COURT:** But you want to cross. Unfortunately,
25 I'm actually in the courthouse. I don't have all my other

1 notes with me.

2 But you say that I issued a ruling or indicated on
3 June 5th that I would allow extra time to explore the
4 previously undisclosed BMD opinion?

5 **MR. CONNETT:** Yes, Your Honor.

6 **MS. CARFORA:** Yes, Your Honor.

7 **THE COURT:** Okay. Well, why don't we do this? I'll
8 just -- so how much time is left anyway at this point?

9 **MR. CONNETT:** So --

10 **THE CLERK:** Your Honor, plaintiff has -- I added ten
11 minutes, so with that addition it's 1 hour and 20 minutes and
12 16 seconds for plaintiff. And defendant has 1 hour 4 minutes
13 and 12 seconds.

14 **THE COURT:** Okay. How long do you expect cross to
15 go, if you include the BMD stuff?

16 **MR. CONNETT:** So cross without BMD, Your Honor, would
17 be about 45 minutes. And then with BMD, I think it would be 15
18 to 20 minutes.

19 **THE COURT:** Okay. Well, let's do this. I'll add
20 another 20 minutes. So we'll reset your clock at an hour 40.
21 How is that?

22 **MR. CONNETT:** Thank you, Your Honor. That's
23 wonderful.

24 And I am a little paranoid about running over my time
25 today because I do want to make sure I have the 30 minutes for

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1 closing. If there is a way -- I don't know if there is a way
2 to -- what would have right now? We would have --

3 MR. WATERS: We have an hour 40.

4 MR. CONNETT: So we would have an hour and 10 minutes
5 today, hour and ten 10 today. Okay. So --

6 MR. WATERS: I'll clock it.

7 MR. CONNETT: Okay. Thank you, Your Honor. We are
8 ready to proceed.

9 THE COURT: Okay. Go ahead. Thank you.

10 CROSS-EXAMINATION

11 BY MR. CONNETT

12 Q. Good afternoon, Dr. Henry.

13 A. Good afternoon.

14 Q. Now, by your own admission you are not an expert on
15 fluoride toxicology; correct?

16 A. Correct.

17 Q. And you are not an expert on fluoride neurotoxicity;
18 correct?

19 A. Correct.

20 Q. And in the course of your career you have never conducted
21 or published a study on fluoride; correct?

22 A. Correct.

23 Q. Prior to this case, you had never once reviewed the
24 scientific literature on fluoride; correct?

25 A. Correct.

1 Q. And prior to the work that you have done on the petition
2 and this case, you had never been involved at the EPA in any
3 fluoride-related projects, regulatory actions, or risk
4 assessments; correct?

5 A. Correct.

6 Q. And at the time of your deposition, Dr. Henry, you did not
7 know how many Americans have fluoridation chemicals added to
8 their drinking water; correct?

9 A. I probably did not.

10 Q. And, in fact, you said that you would be completely
11 guessing as to whether it's 1 million people or over
12 200 million people; correct?

13 A. Correct.

14 Q. So you have been -- today there has been some questions
15 about your assessment of plaintiff's expert's reports. So I'd
16 like to --

17 A. Can I -- I'm having a hard time hearing you.

18 THE COURT: Okay.

19 THE WITNESS: Is there a volume thing I should be
20 looking at?

21 THE COURT: You have a volume on your -- on your end.
22 I'm not having any problem hearing anybody myself. So maybe
23 it's your computer.

24 THE WITNESS: I have it at a hundred.

25 THE COURT: Well, it can't go much further. Maybe

1 just get a little --

2 **THE WITNESS:** Get a little closer?

3 **THE COURT:** Get a little closer, and Mr. Connett can
4 speak up.

5 **BY MR. CONNETT**

6 **Q.** Is this better, Dr. Henry?

7 **A.** Yes.

8 **Q.** Would you agree, Dr. Henry, that before you can have a
9 credible opinion about a report, you need to first read it?

10 **A.** Yes.

11 **Q.** Okay. Now, if an expert report contains 76 references to
12 the Guidelines for Neurotoxicity Risk Assessment in just 69
13 pages of text, do you think that someone who actually has read
14 the report would know that the report discusses the guidelines?

15 **A.** Yes.

16 **Q.** But, Dr. Henry, at your deposition you had -- you had no
17 idea that Dr. Thiessen's report had discussed the guidelines,
18 did you?

19 **A.** I don't recall specifically what context.

20 **Q.** Well, let me ask you, Dr. Henry. At the time I took your
21 deposition, did you know that Dr. Thiessen had discussed
22 Guidelines for Neurotoxicity Risk Assessment in her report?

23 **A.** I don't recall, but -- what I said at the deposition at
24 that time, but she has cited it.

25 **Q.** And I understand that you don't recall what you said at

1 the deposition.

2 I'm asking you a separate question, which is: At the time
3 of your deposition, did you know that Dr. Thiessen had
4 discussed the guidelines in her report?

5 **MS. CARFORA:** Asked and answered.

6 **THE COURT:** Overruled.

7 **A.** Again, I don't think I can recall, but, I mean, I have
8 read it multiple times. She definitely refers to the neurotox
9 guidelines.

10 **MR. CONNETT:** Your Honor, at this time I'm going to
11 introduce impeachment testimony.

12 **THE COURT:** Okay. Give me the page.

13 **MR. CONNETT:** Page 260, Line 18 to Page 261, Line 2.

14 **THE COURT:** Any objection?

15 **MS. CARFORA:** One minute, Your Honor, please.

16 (Brief pause.)

17 **MS. CARFORA:** Mr. Connett, 260, you said?

18 **MR. CONNETT:** 260, Line 18 to 261, Line 2.

19 And, Your Honor, we have two additional excerpts that we
20 would read after this, which say the same thing. We would
21 prefer to read all three excerpts into the record.

22 **THE COURT:** Well, then identify them. Go ahead and
23 identify them.

24 **MR. CONNETT:** The other ones are 261, Line 5 to 15,
25 and Page 263, Line 12 to 20.

1 (Brief pause.)

2 MS. CARFORA: No objection, Your Honor.

3 THE COURT: Go ahead.

4 MR. CONNETT: Mr. Anderson, can you put Page 260?

5 (Document displayed.)

6 BY MS. CARFORA

7 Q. (As read)

8 "QUESTION: And I know that as part of your rebuttal
9 report, you do not discuss Dr. Thiessen's analysis of
10 these guidelines; right?

11 "ANSWER: I don't recall that she discussed these
12 guidelines specifically."

13 MR. CONNETT: You can take that down, Mr. Anderson.

14 If you can put Page 261, Lines 5 to 15?

15 (Document displayed.)

16 BY MR. CONNETT

17 Q. (As read)

18 "QUESTION: So, obviously, you don't have any
19 opinions" --

20 MS. CARFORA: I'm sorry. I'm sorry, Mr. Connett, and
21 I'm sorry to interrupt you.

22 There is an objection in here, and I do object. I
23 maintain that objection for reading this into the record.

24 THE COURT: What's the basis of the objection?

25 MS. CARFORA: It mischaracterizes her testimony. And

1 I can explain that further, if Your Honor wants, but...

2 **THE COURT:** Well, let me read the -- let's see.

3 (Brief pause.)

4 **THE COURT:** Well, you can -- I can read it for that
5 context. The point that counsel is trying to make is the very
6 last part of that sentence.

7 **MR. CONNETT:** Correct.

8 **THE COURT:** Not so much the answer to -- the question
9 to the answer -- the answer to the question?

10 **MR. CONNETT:** Correct. It's the last statement right
11 there, which is pretty clear, and it will be further confirmed,
12 Your Honor, within the next passage.

13 **THE COURT:** So objection overruled. I'm going to
14 ignore the -- whatever implications are of the other parts of
15 the answer or non-answer, but go ahead and read it.

16 **BY MR. CONNETT**

17 **Q.** (As read)

18 **"QUESTION:** So, obviously, you don't have any opinions
19 as to Dr. Thiessen's analysis or application of the
20 1998 guidelines; correct?

21 **"ANSWER:** I guess I would like to know better what
22 aspect of her analysis, because I didn't believe -- I
23 mean, she conducted what I guess she called risk
24 assessments according to TSCA Section 5 guidance, not
25 the neurotox guidelines as I could tell."

1 **MR. CONNETT:** Mr. Anderson, can you now put up on the
2 screen Page 263, Lines 12 to 20?

3 (Document displayed.)

4 **BY MR. CONNETT**

5 **Q.** (As read)

6 **"QUESTION:** And if I have mischaracterized your
7 testimony, please educate me.

8 **"ANSWER:** I don't recall any specific aspect about her
9 discussion of the neurotoxicity guidelines for risk
10 assessment.

11 **"QUESTION:** Okay. And you understand, Dr. Henry, that
12 today is our opportunity to understand your opinions
13 in this case?

14 **"ANSWER:** Yes."

15 **MR. CONNETT:** Thank you, Mr. Anderson.

16 (Document removed from display)

17 **MR. CONNETT:** Okay. At this time, Your Honor, I
18 would like to show the witness a page from Dr. Thiessen's
19 expert report.

20 **MS. CARFORA:** I object to that as hearsay, because
21 the expert reports are not in evidence.

22 **THE COURT:** What's the purpose?

23 **MR. CONNETT:** The purpose is directly to the
24 credibility of the witness's assessment of the report, because
25 it shows very clearly, right from the outset of the report,

1 that the neurotoxicity guidelines are specifically mentioned
2 right in a very, very prominent way. And I think it does go to
3 the -- to the credibility.

4 **THE COURT:** Objection overruled. Go ahead.

5 **BY MR. CONNETT**

6 **MR. CONNETT:** Mr. Anderson, can you put
7 Dr. Thiessen's report on the screen?

8 And can you go to Page 4? Can you highlight that?

9 (Document displayed.)

10 **BY MR. CONNETT**

11 **Q.** Dr. Henry, what does -- can you just read what that
12 section heading says?

13 **A.** (As read)

14 "Based on the hazard identification" --

15 **Q.** Sorry. Can you read what the section heading says?

16 **A.** "Summary of opinions."

17 **Q.** And can you read what the first opinion says in
18 Dr. Thiessen's expert report?

19 **MS. CARFORA:** Objection. Are we reading this into
20 evidence?

21 **MR. CONNETT:** It's a report, Your Honor, that this --
22 that this expert has -- is offering an opinion on in this case,
23 specifically on the credibility of the opinion -- sorry the
24 credibility of the report. I think we're allowed to --

25 **THE COURT:** Objection overruled. Let's move forward.

1 **BY MR. CONNETT**

2 **Q.** Dr. Henry, can you read what Dr. Thiessen's first
3 identified opinion is in her expert report?

4 **A.** (As read)

5 "Based on the hazard identification principles
6 set forth in the EPA's guidelines for neurotoxicity
7 risk assessment, there is sufficient evidence to
8 conclude that neurotoxicity is a hazard of fluoride
9 exposure."

10 **Q.** Okay.

11 **MR. CONNETT:** Thank you, Mr. Anderson. You can take
12 that down.

13 (Document removed from display)

14 **BY MR. CONNETT**

15 **Q.** Now, at your deposition, Dr. Henry, you also did not know
16 that Dr. Thiessen did a margin of exposure analysis, did you?

17 **A.** Again, I don't recall the context in which that question,
18 but she did, and I know she did. She also did an RfD analysis
19 as well.

20 **Q.** Correct. So I'll ask the question: Dr. Henry, at the
21 time I took your deposition, did you know that Dr. Thiessen had
22 done a margin of exposure analysis?

23 **A.** Yes, I did.

24 **Q.** Okay.

25 **MR. CONNETT:** Your Honor, impeachment. Page 335,

1 Lines 3 to 6.

2 **THE COURT:** Okay. Go ahead and put it up.

3 (Document displayed.)

4 **BY MR. CONNETT**

5 **Q.** (As read)

6 **"QUESTION:** But Dr. Thiessen also used an MOE
7 analysis; correct?

8 **"ANSWER:** Sitting here at this moment, I don't
9 recall."

10 **MR. CONNETT:** Thank you Mr. Anderson.

11 (Document removed from display)

12 **BY MR. CONNETT**

13 **Q.** So MOE, Dr. Henry, you would agree with me that that is
14 the acronym for margin of exposure; right?

15 **A.** Yes.

16 **Q.** Now, with respect to Dr. Grandjean's report, one of the
17 criticisms that you offered is that he did not subject his
18 expert report to public notice and comment; correct?

19 **A.** That's a fact.

20 **Q.** And that was one of your criticisms that you had offered
21 of Dr. Grandjean's report; right?

22 **A.** That's possible for sure.

23 **Q.** Well, okay. It's possible, but I want to know --

24 **A.** I don't recall the exact words. Do you have something to
25 refresh?

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1 Q. Well, I'm -- so I'm asking: Do you know whether in last
2 summer when you -- when you offered expert opinions, do you
3 know whether one of your expert opinions was that
4 Dr. Grandjean's report was flawed, in part, because he had not
5 subjected his report to public notice and comment?

6 A. You're asking about what I said last summer or what --

7 Q. Yes. That's what I'm asking you.

8 A. It's possible that I did. And it -- it would be a
9 criticism for a report to support an unreasonable risk finding
10 under TSCA, because TSCA does, in fact, require the peer review
11 be taken.

12 Q. Okay. But, Dr. Henry, when I asked you at your deposition
13 to explain for me how it is that a private citizen like
14 Dr. Grandjean could submit his report for public notice and
15 comment, you did not have an explanation; correct?

16 A. At the time of my deposition we're back at again?

17 Q. Yes.

18 A. I believe somewhere in that sometime -- in the time that
19 we discussed that, that we -- we talked about the third-party
20 guidance as being a way that someone who would follow to submit
21 to EPA a draft risk evaluation, which then, if EPA were to
22 make -- you know, find it to be sufficient, could certainly
23 facilitate that process.

24 MR. CONNETT: Your Honor, at this time I have
25 impeachment testimony.

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1 **THE COURT:** Go ahead.

2 **MR. CONNETT:** It's Page 365, Line 19 to Page 366,
3 Line 9.

4 **MS. CARFORA:** I would just like one moment to catch
5 up with you.

6 I'm sorry. Mr. Connett, did you say Line 9/366?

7 **MR. CONNETT:** 365, Line 19 to 366, Line 9.

8 **MS. CARFORA:** Okay. No -- I mean, no objection.

9 **THE COURT:** Go ahead.

10 **MR. CONNETT:** Paul?

11 (Document displayed.)

12 **BY MR. CONNETT**

13 **Q.** (As read)

14 **"QUESTION:** So I'm asking you specifically in the
15 context of Section 21 *de novo* proceedings in federal
16 court. Can you identify for me a mechanism by which
17 an expert can have their opinions subject to public
18 notice and comment? If the answer is no, you can just
19 say no.

20 **"ANSWER:** No."

21 **MR. CONNETT:** Thank you, Paul.

22 (Document removed from display)

23 **BY MR. CONNETT**

24 **Q.** Now, Dr. Henry, in a situation where there is an abstract
25 and the abstract does not provide any details about whether any

1 potentially confounding factors were controlled for, is it good
2 scientific practice to simply assume that the authors
3 controlled for the potentially confounding factors?

4 A. Is it good scientific practice to assume?

5 Q. Yes.

6 A. No, I wouldn't say that.

7 Q. Now, I'd like to shift towards the risk evaluation rule
8 that was discussed earlier.

9 And, Dr. Henry, in that rule the EPA recognized that
10 weight of the evidence analyses under Section 6 may be, quote,
11 fit for purpose; correct?

12 A. Correct.

13 Q. And the fit for purpose concept reflects EPA's recognition
14 that different weight of scientific evidence review methods may
15 be appropriate with different information; correct?

16 A. I think different weight of evidence analyses, yes.

17 Q. And under this fit for purpose concept, when information
18 and analysis are sufficient to make a risk determination, EPA
19 may decide not to refine its analysis further; correct?

20 A. That is what is stated in the rule.

21 Q. So EPA recognizes that if it has evidence that -- that
22 allows the agency to conduct the comparison of exposure to
23 toxicity based on a fairly straightforward and simple method,
24 it can stop there and need not do further refinement; correct?

25 A. Correct. But that is not at all the case here that we're

1 talking about.

2 **MR. CONNETT:** Your Honor, move to strike the
3 nonresponsive portion.

4 **THE COURT:** Overruled. I'll let it stand.

5 **MR. CONNETT:** Okay.

6 **BY MR. CONNETT**

7 **Q.** So on Friday there was testimony about how EPA has so far
8 been taking a pragmatic approach to systematic review in its
9 risk evaluations under Section 6; and that is correct,
10 Dr. Henry, right?

11 **A.** I don't recall that testimony. Can you refresh my memory?

12 **Q.** So I -- and I apologize. It was a poorly-phrased
13 question. I'll rephrase it.

14 Dr. Henry, is it correct that the EPA has been taking a
15 pragmatic approach to systematic review under its Section 6
16 risk evaluations?

17 **A.** I think we're taking a fairly robust approach. On
18 pragmatic, I guess you can -- it needs a little context, in my
19 view.

20 Pragmatic in the sense that basically everything that --
21 that we have put out, each piece of each risk evaluation we've
22 put out for public comment, and certainly our draft risk
23 evaluations we've put out, not only for public comment but for
24 peer review, and by and large I think if I had to weigh one
25 side or another, we get asked to provide more transparency and

1 more evaluation descriptions.

2 So in being pragmatic, I think that we are applying a
3 robust systematic review method in order to demonstrate that in
4 the end, our risk evaluations, when they are completed, and our
5 risk determinations on which they are based are, in fact, based
6 on best available science and a robust and objective weight of
7 evidence.

8 Q. So one of the criticisms you offered in this case is with
9 respect to Dr. Thiessen's report. You criticized her reliance
10 on the National Research Council's 2006 report with respect to
11 exposure data; right?

12 A. 2006 NRC? Yes.

13 Q. You agree, Dr. Henry, that the NRC is an authoritative
14 institution for scientific reviews; right?

15 A. Yes.

16 Q. And you agree that the NRC's 2006 report provided a
17 comprehensive review of exposure to fluoride in the U.S.,
18 correct?

19 A. I really can't attest to that. I didn't evaluate that
20 report in depth, but it was -- there was a chapter on exposure.
21 And I don't recall exactly what dates were inclusive to it,
22 but, clearly, that report was published in 2006. So that was
23 awhile ago.

24 MR. CONNETT: Your Honor, impeachment. Page 325, 1
25 through 5.

1 **THE COURT:** Okay. Any objection?

2 (Brief pause.)

3 **MS. CARFORA:** No objection.

4 **THE COURT:** Go ahead.

5 (Document displayed.)

6 **BY MR. CONNETT**

7 **Q.** (As read)

8 **"QUESTION:** Do you know that the NRC did a
9 comprehensive review of exposure to fluoride in the
10 United States?

11 **"ANSWER:** I don't recall the year, but I'm aware."

12 **MR. CONNETT:** Thank you, Paul.

13 (Document removed from display)

14 **BY MR. CONNETT**

15 **Q.** And, Dr. Henry, you agree that an NRC review of exposure
16 to a chemical is the type of material that qualifies as best
17 available science; right?

18 **A.** I don't think that necessarily by a blanket statement I
19 could agree with that.

20 **MR. CONNETT:** Your Honor, impeachment. Page 328, 1
21 through 5.

22 **THE COURT:** Okay.

23 **MS. CARFORA:** 328. No objection.

24 **THE COURT:** Go ahead.

25 (Document displayed.)

1 BY MR. CONNETT

2 Q. (As read)

3 "QUESTION: Would you say that the NRC review of the
4 exposure to a chemical substance is the type of
5 material that qualifies as best available science?

6 "ANSWER: Yes."

7 And, Dr. Henry --

8 MR. CONNETT: Paul, thank you. You can take that
9 down.

10 (Document removed from display)

11 BY MR. CONNETT

12 Q. Dr. Henry, you were not aware of any data published
13 subsequent to the NRC report which contradicts NRC's exposure
14 estimates; correct?

15 A. There has been an additional, more comprehensive, updated
16 literature search and calculations of exposures since 2006.

17 Q. Right. But my question is: You're not aware of any data
18 on water intake published subsequent to the NRC report which
19 contradicts NRC's estimates; right?

20 A. Well, exposure data is like a continuous measurement. So
21 it's not a contradiction. It's a different dataset over time.

22 MR. CONNETT: Your Honor, impeachment.

23 THE COURT: All right.

24 MR. CONNETT: 327, Lines 18 to 21.

25 THE COURT: What page?

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1 **MR. CONNETT:** 327, Lines 18 to 21.

2 **THE COURT:** Okay.

3 **MS. CARFORA:** No objection.

4 **THE COURT:** Go ahead.

5 (Document displayed.)

6 **BY MR. CONNETT**

7 **Q.** (As read)

8 **"QUESTION:** Are you aware of any published data
9 subsequent to the NRC review that contradicts NRC's
10 estimates as to exposure to fluoride?

11 **"ANSWER:** No, I am not."

12 **MR. CONNETT:** Thank you, Paul.

13 (Document removed from display)

14 **BY MR. CONNETT**

15 **Q.** Now, as you mentioned, Dr. Henry, there has been a
16 subsequent report in 2019 by the EPA, where EPA provided sort
17 of a comprehensive review of water intake data; right?

18 **A.** Yes.

19 **Q.** And in that review, EPA identified water intake data that
20 it characterized as the most scientifically sound and
21 up-to-date data to use for risk assessment; correct?

22 **A.** I -- those are probably the words in the *Exposure Factors*
23 handbook, based on that recent analysis.

24 **Q.** And would you agree that using a pragmatic approach to
25 systematic review under Section 6, that data that the EPA has

1 characterized as recently as 2019 as the most scientifically
2 sound and up-to-date data to use for risk assessment, that that
3 would be appropriate data to use for risk evaluation?

4 A. I think it's potentially, but I think that as a matter of
5 course, under TSCA we would still look and search to see if
6 there was anything newer.

7 Q. Okay.

8 A. And especially because, you know, again, that *Exposure*
9 *Factors* handbook has a wide array of types data. Certainly,
10 EPA, including OPPT, looks to it to find information and, you
11 know, especially that one which is based on a systematic review
12 of all of the various most up-to-date information.

13 Sure, but I think that, again, we probably, more than
14 likely, just take a quick look to see if there is anything
15 newer.

16 Q. Okay. Now two weeks before I took your deposition, you
17 had re-read EPA's Guidelines for Neurotoxicity Risk Assessment;
18 correct?

19 A. I don't recall if I said exactly two weeks, but it's
20 possible it's there.

21 Q. Well, you would agree with me that you had re-read those
22 guidelines shortly before your deposition; correct?

23 A. If that's what I said, then that is true.

24 Q. Well, I understand, and in normal conversations I probably
25 wouldn't inquire any further.

1 But do you -- did you or did you not, Dr. Henry, re-read
2 those guidelines last summer?

3 **A.** As I recall, yes, I did.

4 **Q.** Okay. And you agree, Dr. Henry, that the Guidelines for
5 Neurotoxicity Risk Assessment can be used for risk evaluations
6 under TSCA; correct?

7 **A.** They serve as a guideline on how to conduct a risk
8 assessment generally. TSCA does put some additional context
9 around that.

10 **Q.** But they can be -- in the risk evaluation -- I understand
11 that the risk evaluation rule provides additional
12 considerations, but the -- you recognize, and EPA recognizes,
13 that the Guidelines for Neurotoxicity Risk Assessment can be
14 used as part of a risk evaluation under Section 6; correct?

15 **A.** All of the Risk Assessment Forum guidelines are there to
16 guide EPA risk assessors on the general principles and
17 processes for conducting the various types and considerations
18 that assessors should think about in doing so.

19 But each and every one of those guidelines are very, very
20 clear that they are not, you know, rules in themselves and that
21 they are there as a guide to be implemented within other
22 contexts.

23 And they also, because they were developed to try and not
24 be so specific as to become out-of-date a very short period of
25 time, they -- again, they don't tend to be overly prescriptive.

HENRY - CROSS / CONNETT

1 Q. Now, you agree, Dr. Henry, that the criteria identified in
2 the Guidelines for Neurotoxicity Risk Assessment are very
3 similar, if not the same, as the kinds of criteria that you use
4 in conducting a systematic review and evaluating literature;
5 correct?

6 A. I think I need to know better what criteria you're
7 referring to to answer.

8 Q. Well, I am directly quoting your deposition. So I'm just
9 asking: Do you agree with that statement or not?

10 A. I think that there are certain criteria in the neurotox
11 guidelines which have to do with consistency and validity and
12 some of those things. So those are the kinds of considerations
13 for a weight of evidence, but they aren't -- that guidance does
14 not provide very specific, what is considered study evaluation
15 criteria.

16 MR. CONNETT: Your Honor, at this time I have
17 impeachment. Page 253, Lines 3 to 12.

18 THE COURT: Any objection?

19 (Brief pause.)

20 MS. CARFORA: Mr. Connett, 253 starts in the --
21 Line 3 starts in the middle of a question, or maybe I'm in the
22 wrong place.

23 MR. CONNETT: Well, right. I'm fine with -- so I'm
24 fine -- it's just a little bit of a stumble to start the
25 question, but I can read the whole question if that's

1 important.

2 **THE COURT:** All right. Go ahead.

3 **MR. CONNETT:** Paul, can you put up 252, Line 21?

4 (Document displayed.)

5 **BY MR. CONNETT**

6 **Q.** (As read)

7 **"QUESTION:** Now, do these guidelines -- and I know I
8 haven't given you the full document, so it's going to
9 go on your recollection, but do these guidelines
10 require any systematic review procedure?

11 **"ANSWER:** There is a whole chapter on various things
12 to consider, particularly -- this particular guideline
13 has a lot of information for evaluating studies and
14 many, many of those are very similar, if not the same,
15 as the kinds of criteria that you use in conducting a
16 systematic review and evaluating literature under that
17 umbrella."

18 **MR. CONNETT:** Thank you, Paul.

19 (Document removed from display)

20 **BY MR. CONNETT**

21 **Q.** And, Dr. Henry, you would agree that the predefined
22 factors set forth in the guidelines are very much the same
23 things you do in what we call a systematic review; correct?

24 **A.** Not today.

25 **Q.** But you did at your deposition?

1 **A.** Similar in concept, but in the specific detail around some
2 of the evaluation criteria in particular, to get at bias and so
3 forth. The neurotox guidelines, as I mentioned, tried not to
4 than too prescriptive so they would, you know, last, if you
5 will.

6 So, again, evolving science and practice in risk
7 assessment of -- landed in a place where the actual practice
8 that we're using is much more specific.

9 **MR. CONNETT:** Your Honor, I do have impeachment here
10 again. It's Page 253, Lines 15 to 254, Line 2.

11 **THE COURT:** Any objection?

12 **MS. CARFORA:** No objection.

13 **THE COURT:** Go ahead.

14 (Document displayed.)

15 **BY MR. CONNETT**

16 **Q.** (As read)

17 **"QUESTION:** Do these guidelines require a systematic
18 review method?

19 **"ANSWER:** At the time that this guideline was
20 published, what was in this guideline, from what I
21 read, particularly under Hazard, are very much the
22 same things you do in what we call a systematic review
23 today."

24 **MR. CONNETT:** Thank you, Paul.

25 (Document removed from display)

1 BY MR. CONNETT

2 Q. And, Dr. Henry, do you agree that if one follows the
3 guidelines, they will have effectively done a systematic
4 review; right?

5 A. If they document and show the actual work has been
6 conducted and that those criteria have specifically been
7 applied in evaluating individual studies.

8 Q. Okay. Now, for you, Dr. Henry, it is very important that
9 citizens in Section 21 proceedings do everything the way that
10 EPA does; right?

11 A. I thought I talked about there earlier, but no. Again,
12 you don't have to have exactly the same format and, you know,
13 tables and sections and form per se, but the requisite
14 scientific basis needs to be there, and certainly -- so, again,
15 some demonstration that's complete, clear, transparent, around
16 whether or not the data and studies being used are best
17 available science needs to be there and, also, some kind of
18 integrative weight of evidence.

19 If a Section 21 petition comes to EPA and within 90 days a
20 risk determination is to be made, I would expect that it needs
21 to be pretty robust around all of these other requirements to
22 get there.

23 Q. Okay. Now, I'd like to talk briefly, Dr. Henry, about
24 what you did in this case and how it stacks up to the way EPA
25 does things under Section 6.

HENRY - CROSS / CONNETT

1 Now, you were talking earlier that you were one of the
2 primary authors of EPA's response to plaintiff's petition;
3 correct?

4 **A.** I was a primary -- yes, primarily involved on the team,
5 yes.

6 **MR. CONNETT:** At this time, Your Honor, I would like
7 to show the witness a statement from that petition response.

8 **THE COURT:** Any objection?

9 **MS. CARFORA:** No objection, Your Honor.

10 **MR. CONNETT:** Paul, can you put on the screen Page 10
11 of the PDF -- sorry, it's not Page 10. Sorry. This is a --
12 this is EPA's Exhibit 514, and it's Page 11881.

13 (Document displayed)

14 **BY MR. CONNETT**

15 **Q.** So here, Dr. Henry, EPA wrote:

16 "After careful consideration EPA denied the TSCA
17 Section 21 petition, primarily because EPA concluded
18 that the petition has not set forth a scientifically
19 defensible basis to conclude that any persons have
20 suffered neurotoxic harm as a result of exposure to
21 fluoride in the U.S. through the purposeful addition
22 of fluoridation chemicals to drinking water."

23 Did I read that correctly?

24 **A.** Hold on. I've got to move my little box.

25 Yes.

HENRY - CROSS / CONNETT

1 **MR. CONNETT:** Paul, you can put that down.

2 (Document removed from display)

3 **BY MR. CONNETT**

4 **Q.** And consistent with the EPA's response to the plaintiff's
5 petition, in your expert report in this case you concluded
6 that:

7 "Fluoridation does not present a risk of
8 neurotoxicity because there is insufficient evidence
9 to conclude that fluoridation causes neurotoxicity at
10 the concentration of .7 milligrams per liter."

11 Correct?

12 **A.** Again, I -- I don't know exactly what you're reading from,
13 but that sounds pretty close to one of my declaration
14 conclusions.

15 **Q.** Do you stand by that opinion, Dr. Henry?

16 **A.** Yes.

17 **Q.** Okay. So you used a causation standard for assessing
18 risk; right?

19 **A.** No, not necessarily.

20 **Q.** Well, your own -- your own expert report, Dr. Henry, when
21 you talk about whether we met our burden, you specifically say:

22 "We haven't shown that fluoridation causes
23 neurotoxicity at .7 milligrams per liter."

24 Right?

25 **A.** Yes.

1 Q. So you used a causation standard?

2 A. That's what we wrote -- that's what I wrote, yes.

3 Q. But, Dr. Henry, to be clear -- and the Court has the draft
4 risk evaluations in evidence in this case, so the Court can
5 review those risk evaluations.

6 EPA has never once in any of its risk evaluations to date
7 under Section 6 used a causation standard, has it?

8 A. No. You don't have to show absolute causation.

9 Q. That's what you held the plaintiffs to in this case. You
10 held the plaintiffs to a standard that EPA has never once held
11 any other chemical under Section 6; right?

12 MS. CARFORA: Objection, broad. Overbroad.

13 THE COURT: Overruled.

14 A. Can you repeat the question?

15 BY MR. CONNETT

16 Q. You held the plaintiffs to a burden of proof that EPA has
17 not held a single chemical under Section 6 before; correct?

18 A. By the words on the page, I guess that's -- that's true,
19 but it was really my -- my opinion was based mostly on the
20 methodological problems.

21 Q. I want to talk about one risk evaluation that EPA has
22 done, the NMP risk evaluation. I know it's draft form, but I
23 assume you're familiar with that.

24 You're familiar with the NMP risk evaluation, Dr. Henry?

25 A. Yes.

1 Q. In that risk evaluation EPA found that some conditions of
2 use presented unreasonable risks to human health; correct?

3 A. Correct.

4 Q. And in that evaluation EPA selected reproductive health
5 problems as the critical health point -- health endpoint for
6 chronic exposure; correct?

7 A. Again, I'd have to have a refreshment. Again, we --
8 typically, EPA will consider all of the potential hazards, so I
9 can't speak without consulting the document. It's not the
10 only -- I don't believe it's the only hazard that was
11 considered.

12 Q. But for what you selected as the critical endpoint in your
13 unreasonable risk determination, that critical endpoint is
14 identified as reproductive problems; correct?

15 A. So, again, under TSCA risk evaluations, we don't typically
16 assess just one hazard or toxicity endpoint. We do the hazard
17 assessment to broadly look for a variety.

18 And so, again, without -- without being able to consult
19 back to the table of all of the different PODs that may have
20 been brought forward, I can't recall. These are very extensive
21 risk evaluations.

22 And so I do know that reproductive or developmental is one
23 of the toxicity endpoints evaluated, but I do not know that it,
24 sitting here today, it is the only one.

25 Q. Okay. Fair enough. I understand. It's a long document,

1 and I won't hold you to every detail in it.

2 But fair to say, Dr. Henry, that EPA did not require
3 evidence showing that human exposures to NMP under the
4 conditions of use caused adverse effects on human health;
5 correct?

6 **A.** No. And I don't believe there was human data for that
7 chemical.

8 **Q.** Right. EPA had no human data on the critical endpoint in
9 the U.S. It had no human data in Canada. It had no human data
10 in Mexico. It had no human data in China. It had no human
11 data at high levels. It had no human data at low levels;
12 correct?

13 **MS. CARFORA:** Objection. Compound.

14 **THE COURT:** Overruled.

15 **A.** My recollection here today is that NMP did not include
16 human data as data used for making the risk characterization or
17 risk determination.

18 **BY MR. CONNETT**

19 **Q.** Now, based on the animal studies that the EPA reviewed,
20 EPA, for the chronic health endpoint, calculated a BMDL of the
21 dose associated with some -- with some effects in the animals;
22 correct?

23 **A.** Can you repeat that?

24 **MR. CONNETT:** Well, Your Honor at this point may I
25 have permission to show the witness Plaintiff's Exhibit 49,

1 which is already in evidence?

2 **THE COURT:** What is it?

3 **MR. CONNETT:** It's the risk evaluation for NMP.

4 **THE COURT:** Well --

5 **MS. CARFORA:** Well, my only concern is is there a
6 question pending? And are you using the document for something
7 related to the question that I believe is pending.

8 **MR. CONNETT:** I can just withdraw the question and
9 start again.

10 **THE COURT:** And so you are intending to then publish
11 it and ask questions about it?

12 **MR. CONNETT:** Correct, Your Honor. It's in evidence.

13 **THE COURT:** Okay.

14 **MR. CONNETT:** Is there an objection?

15 **MS. CARFORA:** No objection.

16 **THE COURT:** Go ahead.

17 (Document displayed.)

18 **BY MR. CONNETT**

19 **Q.** So, Dr. Henry, I'm showing you Page 204 of the NMP risk
20 evaluation. And you see the table here is called "Summary of
21 Derivation of the PODs for Reproductive and Developmental
22 Effects Following Chronic Exposure to NMP"?

23 **A.** Yes. What I'm not clear about, without seeing the other
24 tables, is whether this is the table of all of the PODs that
25 were derived from the full body of reproductive and

1 developmental studies, or if this is the table which slims it
2 down to what's going to be carried forward into the risk
3 estimation.

4 Q. Okay. So since you can't recall that, I will not ask
5 further questions.

6 A. I mean, every risk evaluation shows, like, a full table of
7 acceptable high quality studies and what the PODs would be, and
8 on the basis of that is where a judgment is made on which ones
9 we'll take forward to the multiple exposure scenario.

10 Unlike an IRIS assessment -- well, and they've changed
11 also. It used to be you that would take this body and evidence
12 and you would trim it down and pick one critical endpoint and
13 study and carry it all through. But, again, because --
14 especially under TSCA, there are so very many different
15 exposure scenarios associated with the variety of conditions of
16 use, we for sure don't do that.

17 You could use a different study with a different POD for a
18 different exposure scenario. So I saw that table, that I know
19 there is a corresponding table where they pull all the PODs
20 that are carried forward to doing the risk assessment. I just
21 can't tell without the broader context whether this the more
22 comprehensive table of PODs or those used in specific exposure
23 scenarios.

24 Q. Understood. Okay. I'm going to show you now another page
25 from the document, which is Page 312. This, again, is

1 Plaintiff's Exhibit 49.

2 (Document displayed.)

3 **BY MR. CONNETT**

4 **Q.** And here, Dr. Henry, this shows one of the conditions of
5 use for which EPA made an unreasonable risk determination;
6 correct?

7 **A.** Yes, by workers.

8 **Q.** All right. And the driver of the risk here is
9 reproductive effects; correct?

10 **A.** Yes.

11 **Q.** And the -- the margin of exposure, the actual margin of
12 exposure is identified here as 25; correct?

13 **A.** Yes. That's the risk estimate.

14 **Q.** And these are highly exposed workers. This is the high
15 end scenario for workers; correct?

16 **A.** Correct.

17 **Q.** Okay. And so what this 25 means, Dr. Henry -- and tell me
18 if I get this incorrect -- this means that highly exposed
19 workers under this condition of use received 1/25th the point
20 of departure from the animal data; correct?

21 **A.** I have not heard it expressed in that manner, so I'd have
22 to do some math.

23 Yes. It's a simple division equation of comparing the
24 exposure estimate to the POD. So I guess I never heard it
25 expressed quite that way, but yes.

1 Q. So with that -- that margin, that margin from the point of
2 departure from animal data to human exposure, although it
3 was -- although human exposure was 25 times less than the
4 animal point of departure, EPA found that to present an
5 unreasonable risk; correct?

6 A. Yes, because the benchmark MOE was 30.

7 Q. Okay. Now, in this case neither you nor Dr. Tsuji nor
8 Dr. Chang made any attempt to estimate what the hazard level is
9 for fluoride neurotoxicity; correct?

10 A. No, none of us conducted or attempted a risk evaluation.

11 Q. And neither you nor Dr. Tsuji nor Dr. Chang made any
12 attempt to determine what the acceptable margin would be
13 between the estimated hazard level for fluoride and the human
14 exposure level to fluoride under the conditions of use for
15 fluoridation; correct?

16 A. Again, none of us have conducted an actual risk
17 evaluation.

18 Q. Okay.

19 A. We did look at a lot of data, the spread of data that was
20 of quality around where -- the neighborhood of the PODs.

21 Q. Okay. So now I'd like to talk a little bit about
22 uncertainty factors. And in the NMP risk evaluation, EPA used
23 developmental toxicity as the critical health endpoint for
24 acute exposure; correct?

25 A. I believe so.

1 Q. And --

2 A. But I -- I don't recall if -- I don't believe it was
3 developmental neurotoxicity. I believe it was regular
4 developmental, but I don't recall the exact effects, what is
5 the difference, which could relate to uncertainty factors.

6 Q. So, Dr. Henry, in -- for the -- for your point of
7 departure for the developmental toxicity, EPA selected animal
8 data that -- where the -- where the rats had been exposed
9 during pregnancy; correct?

10 A. I'd have to again see what kind of study was actually
11 conducted, but if it was an OECD Guideline 422 or a 414, that
12 would be correct.

13 Q. Right. But you'd agree that if the concern is about
14 developmental toxicity during the in utero period, that you
15 would obviously use animal studies where the exposure occurred
16 in utero; right?

17 A. That would be optimal. You'd have an actual study
18 designed to detect developmental toxicity.

19 Q. So I'm going to show you Page 202 of the NMP risk
20 evaluation. And you see this Table 310 is titled "Summary of
21 Derivation of the PODs for Fetal Resorptions and Fetal
22 Mortality Following Acute Exposure to NMP." Do you see that?

23 A. Yes.

24 Q. And so the endpoint here for the acute exposures is fetal
25 resorptions and fetal mortality; right?

1 **A.** Yes. It clarifies.

2 **Q.** And, obviously, fetal resorptions and fetal mortality can
3 only be studied if there is exposure during the utero period;
4 right?

5 **A.** That's correct. And these tests are designed to go in
6 after the fact and count.

7 But you can actually go in and count resorptions because
8 it leaves a mark in the uterus, and then mortality would be
9 where you find an actual dead fetus.

10 **Q.** Right. And so you would agree with me, Dr. Henry, that
11 the population studied in these animal studies -- namely, the
12 pregnant mom and the offspring -- that those studies were
13 dealing with the most susceptible population for this endpoint;
14 correct.

15 **A.** Can you restate that?

16 **Q.** You would agree that if the concern is developmental
17 toxicity and the studies are actually investigating animals
18 exposed in utero, that these animal studies would be capturing,
19 in terms of life stage, the most susceptible population;
20 correct?

21 **A.** Yes. That's the developmental toxicity test is meant to
22 measure.

23 **Q.** And EPA, when it determined what uncertainty factor to
24 apply, it applied an uncertainty factor of ten to account for
25 intraspecies variables; correct?

1 A. Human intraspecies, yes.

2 Q. So the animal data was focused on the most susceptible
3 life stage, and EPA applied an uncertainty factor of ten to
4 account for human-to-human variation; correct?

5 A. Correct.

6 Q. Now, we were talking -- in your declaration you rely upon
7 and talk about the NRC's 1994 blue book; right?

8 A. '94?

9 Q. Yeah. The 1994 NRC book on risk assessment.

10 A. What's the title? I don't remember one called the blue
11 book.

12 Q. It's science and -- let's see.

13 A. That's the silver book.

14 Q. Sorry, the silver book. Thank you.

15 The 1994 NRC book entitled *Science and Judgment in Risk*
16 *Assessment*.

17 A. All right. That's the silver book. I didn't know it was
18 called the blue book.

19 Q. So I'll just -- we'll just refer to it as the 1994 NRC
20 report. Does that make sense?

21 A. Yes. Thank you.

22 Q. And in that report the NRC talked about the importance of
23 using -- of being consistent in how we apply inference
24 guidelines or defaults in risk assessment; right?

25 A. I suppose it did. There has been a lot of NRC reports

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1 around application of uncertainty factors. This is a -- a
2 subject of much debate and suggestion in the world of risk
3 assessment.

4 **Q.** And in that NRC report NRC stated that:

5 "Without applying these default factors
6 consistently, risk assessments might be manipulated on
7 an ad hoc basis according whether regulating a
8 substance is thought to be politically feasible."

9 Correct?

10 **A.** I don't recall the report. If you have the words in front
11 of you, I would appreciate seeing that that's exactly what they
12 were saying.

13 **MR. CONNETT:** Your Honor, may I refresh the witness's
14 recollection?

15 **THE COURT:** Yes.

16 (Document displayed.)

17 **BY MR. CONNETT**

18 **Q.** And, Dr. Henry, can you see this on your screen?

19 **A.** Yeah. If I recall, this -- in this time period, you can
20 see they are talking about the '83, that there -- one of the
21 mean crux of this particular NRC report, because there have
22 been several on the topic, was that while agencies across the
23 government were utilizing risk assessment methods and following
24 the paradigm, that there was a little -- quite a bit of
25 variation on how everybody was doing it.

1 So they were calling essentially for some kind of
2 agreement or some kind of guidance around what should be sort
3 of the standard or default approach. There has definitely been
4 subsequent NRC reports about trying to get away from using
5 these default uncertainty factors, however.

6 **Q.** Do you agree, though, with this principle we see here
7 written on the page?

8 **MS. CARFORA:** Objection. Just to --

9 **MR. CONNETT:** Your Honor, I will withdraw the
10 question. I'll withdraw the question.

11 **MS. CARFORA:** Thank you.

12 **BY MR. CONNETT**

13 **Q.** So let's then -- I know that's a 1994 report. So I'd like
14 to ask you now about the 2009 report that the NRC wrote on risk
15 assessment. And you're familiar with that report; correct?

16 **A.** The silver book, yes.

17 **Q.** And would you agree that the NRC's 2009 report on risk
18 assessment is an authoritative report in the field; correct?

19 **A.** Well, it was commissioned by EPA to give us advice on
20 areas in which to improve our risk assessment.

21 So, again, the way that often these work is that a federal
22 agency will charge the NRC to give them advice and
23 recommendations, and then a contract is set up, and then they
24 convene people to give us advice.

25 **Q.** Now, I'm going to summarize what I understand to be one of

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1 the recommendations of the NRC 2009 report, and I want to ask
2 you if you think it's a correct summary. Okay?

3 **A.** Of the 2009?

4 **Q.** Correct.

5 Okay. Because of the effort that EPA has invested in
6 selecting its current defaults and the consistency that
7 defaults confer on the risk assessment process, the use of an
8 alternative to the default in specific cases faces a
9 substantial hurdle and should be supported by specific theory
10 and evidence. The committee recommends that EPA adopt an
11 alternative assumption in place of a default when it determines
12 that the alternative is clearly superior; that is, that it's
13 plausibility clearly exceeds the plausibility of the default.

14 Dr. Henry, would you agree that that's one of the
15 recommendations that the NRC made to the EPA in 2009?

16 **MS. CARFORA:** Your Honor, I object as hearsay,
17 because he just read that entire paragraph into the record.
18 I would --

19 **THE COURT:** It's not hearsay because it's not
20 evidence until she says "yes" or "no."

21 **MS. CARFORA:** Well, I appreciate that, but he just
22 read out of -- he just read out of the document to the witness.

23 So it's in the record now and the document doesn't --

24 **THE COURT:** It's not --

25 **MS. CARFORA:** The witness doesn't have the document

1 in front of her.

2 **THE COURT:** It's part of the question, so it's not in
3 evidence my book.

4 Objection overruled. She can answer.

5 **A.** Can you restate it? Sorry.

6 **BY MR. CONNETT**

7 **Q.** So I mean, Dr. Henry, first off, you agree that the NRC's
8 2009 report is the -- is one of the seminal NRC reports on risk
9 assessment that you, yourself, have cited throughout this
10 litigation; correct?

11 **A.** Yes.

12 **Q.** Okay.

13 **A.** It is advice to EPA on how to improve risk assessment
14 efforts.

15 **Q.** And isn't it true, Dr. Henry, that the NRC recommended
16 that the use of alternatives to a default in any given risk
17 assessment should be supported by specific theory and evidence;
18 correct?

19 **A.** I would say it slightly different; that they were
20 encouraging us. This is one of the areas that they
21 specifically were asked to examine, and they did a lot of words
22 to encourage us to find ways to get off of these defaults.

23 **Q.** But the committee recommended --

24 **A.** But you do have to support them.

25 **Q.** Right. And would you agree that the NRC concluded that

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1 the use of an alternative to a default in any given risk
2 assessment must be shown to be clearly superior to the default?

3 **A.** Again, I don't know about that word "superior" word seeing
4 the words.

5 But again, of course, we would want to have an explanation
6 or a rationale. We are encouraged on the one hand to move away
7 from defaults. However, science limited -- is limited in some
8 of these areas of uncertainty, so we have to find tools and
9 methods and scientific underpinnings to move off of default.
10 That is the current state of practice.

11 **Q.** Okay. So I only have a few minutes left here, and I don't
12 want to go one minute over. So we are, what, we're about 59
13 minutes in. So I have 10 minutes left here.

14 Let's talk about benchmark dose analysis. In critiquing
15 Dr. Grandjean's calculations in this case you relied upon EPA's
16 benchmark dose technical guidance; correct?

17 **A.** Yes.

18 **Q.** One of your main criticisms of Dr. Grandjean's BMD
19 analysis is that he didn't provide enough information for you
20 to assess his analysis; right?

21 **A.** Correct.

22 **Q.** But neither you nor anybody at the EPA ever asked
23 Dr. Grandjean to provide additional information to show what he
24 did and how he did his analysis; correct?

25 **A.** No. I didn't even know that was an option.

1 Q. Okay. You never talked with the attorneys to ask whether
2 you might be able to get additional data?

3 A. Well, my recollection is that we had a very short
4 turnaround on reviewing these in general.

5 Again, I guess my expectation is if you're providing me
6 with something that is supposed to be the basis of making this
7 determination, that it needs to have -- it needs to be it --
8 it.

9 Q. Well, Dr. Henry, didn't Dr. Grandjean and his BMD analysis
10 identify the published studies that he was relying upon?

11 A. He did.

12 Q. And --

13 A. I believe in -- again, there were two different reports
14 with two -- the two different studies that have been discussed
15 at length here in the last week.

16 One -- I have a recollection that -- that it wasn't
17 even -- one of the two was not yet published in the scientific
18 literature at that time.

19 The first report didn't have the Canada study at all. It
20 only had ELEMENT. And I don't know for sure, in my
21 recollection here, exactly how much of that information.

22 But, again, I guess I just never thought it was up to me
23 to go and find the data.

24 Q. Fair enough.

25 A. In an EPA risk assessment it's always provided.

1 Q. Fair enough.

2 A. But because, again, this is a --

3 MR. CONNETT: Your Honor, at this point I think the
4 witness is going on a little bit beyond --

5 THE COURT: Yeah. Let's go to the next question.

6 BY MR. CONNETT

7 Q. So, Dr. Henry, is it fair to say that the EPA has access
8 to studies that are published in the open literature?

9 A. Yes.

10 Q. And you mentioned the ELEMENT study that Dr. Grandjean
11 relied upon. That's Bashash 2017; correct?

12 A. Correct.

13 Q. Dr. Grandjean, in his benchmark dose analysis, talked
14 about extracting the data points from the scatter plot;
15 correct?

16 A. I believe the word was digitizing.

17 Q. And did EPA at any point in this litigation attempt to do
18 that?

19 A. With that dataset to recreate his analysis?

20 Q. Yes.

21 A. No.

22 Q. Okay. I take it that that is something that the EPA has
23 the ability to do?

24 A. What? Go to the journal and digitize the data?

25 Q. Correct.

1 A. Yes.

2 Q. And I take it that EPA also has the ability to take
3 coefficients and do a BMR analysis of coefficient regressions
4 in published papers; right?

5 A. Can you restate that?

6 Q. Well, I'll move on.

7 A. You need the data to get the coefficients.

8 Q. Now, the BMD guidance that you rely upon, the EPA BMD
9 guidance, that is not a document that is binding on EPA or any
10 regulated entity; correct?

11 A. None of the EPA guidelines are binding.

12 Q. Okay. And the BMD guidance specifically says that it's
13 not designed to replace the expert judgments of toxicologists
14 and others who addressed the hazard characterization issues in
15 risk assessment; right?

16 A. I'll take your word for it, but it sounds like something
17 we would say.

18 Q. And the guidelines -- the guidance that you're relying
19 upon, the BMD guidance, recognizes that expert evaluation and
20 judgments on issues such as study quality and toxicological
21 significance are beyond the scope of the guidance; right?

22 A. Yes.

23 Q. Okay. And, Dr. Henry, you have no opinion on
24 Dr. Grandjean's use of one IQ point for his BMR; correct?

25 A. I have no opinion?

HENRY - CROSS / CONNETT

1 Q. Correct.

2 A. Here today?

3 Q. I'm asking: Do you have an opinion on Dr. Grandjean's use
4 of one IQ point for his benchmark response?

5 A. I believe that I don't think that he well justified and
6 provided the strong basis for doing so.

7 MR. CONNETT: Your Honor, I have an impeachment. On
8 Page 358, Line 18 to Page 359, Line 1. And this will be my --
9 the last question for the exam.

10 THE COURT: Any objection?

11 MS. CARFORA: Can you tell me -- you said 358? What
12 was the line? I'm sorry.

13 MR. CONNETT: 18, to 359/1.

14 MS. CARFORA: I object because it's a different
15 question than what you just posed.

16 If you want to ask her the same question and see what she
17 says, go ahead, but what you just asked her is a different
18 question.

19 MR. CONNETT: Your Honor, can --

20 THE COURT: Why don't you put it up so I can see it,
21 what you asked, because I don't have it with me here.

22 (Document displayed.)

23 THE COURT: Scroll down? Oh, I see.

24 Well, it's close enough. Go ahead and read it.

25

HENRY - CROSS / CONNETT

1 BY MR. CONNETT

2 Q. (As read)

3 "QUESTION: So do you have any opinions, one way or
4 the other, as to whether a loss of one IQ point is
5 suitable for use as a BMR, benchmark response?

6 "ANSWER: No, I don't have an opinion."

7 MR. CONNETT: And, Your Honor, at this time
8 plaintiffs have no further questions.

9 THE COURT: All right. Anything on redirect?

10 MS. CARFORA: Yes, Your Honor. Can I get a two or
11 three-minute recess, please?

12 THE COURT: Okay. Three minutes.

13 MS. CARFORA: Thank you.

14 THE CLERK: Court is in recess.

15 (Whereupon there was a recess in the proceedings
16 from 4:16 p.m. until 4:20 p.m.)

17 THE CLERK: Court is now in session.

18 THE COURT: All right. Ms. Carfora, you may resume.

19 MS. CARFORA: Yes. Thank you, Your Honor.

20 I'm sorry, I -- I do not see Dr. Henry. Is she on the --
21 on everybody else's screen?

22 THE WITNESS: Hi, can you hear me?

23 It never happened a single time last week, but this week
24 Zoom keeps cutting me off and disappearing from my computer.
25 So I just came all the way back in. I had to dial mode and

HENRY - EXAMINATION / CARFORA

1 call back in.

2 **THE CLERK:** Okay. I just promoted her as a panelist
3 again. I'm not sure what happened because Zoom has been doing
4 this randomly.

5 **THE WITNESS:** I know. It's just suddenly this week.
6 This is, like, the fifth time I have had to download it.

7 Here I am. I'm back.

8 **MS. CARFORA:** Thank you.

9 **THE COURT:** Go ahead, Ms. Carfora.

10 **REDIRECT EXAMINATION**

11 **BY MS. CARFORA**

12 **Q.** Dr. Henry, did you read Dr. Thiessen's -- all three of
13 Dr. Thiessen's expert reports?

14 **A.** Yes. Multiple times.

15 **Q.** In the first report that Dr. Thiessen wrote that
16 Mr. Connett was referring to, in your opinion, did Dr. Thiessen
17 discuss risk assessment guidelines or did she just cite to
18 them?

19 **A.** My recollection is she cited to them. She also cited to
20 our Section 5, the way -- our methodologies for conducting
21 those. So it was kind of intermingled. In particular, in the
22 MOE analysis she was referring multiple times to that. So I
23 found that confusing or puzzling.

24 **Q.** And in your opinion, did Dr. Thiessen document her
25 scientific justification or analysis offered for her expert

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1 opinion?

2 **MR. CONNETT:** Your Honor, this is actually beyond the
3 scope.

4 **THE COURT:** I believe it is, on this point.

5 **MS. CARFORA:** Well, if I could, Your Honor -- I don't
6 want you -- he showed her the report and he asked her questions
7 about the report. He specifically asked her about discussions,
8 not about citing. And he specifically asked her about whether
9 the -- if somebody followed the guidelines, whether or not --

10 **THE COURT:** I'll let you ask it, if it's along the
11 lines of the guidelines. But your last question, seemed to me,
12 was broader than that.

13 **MS. CARFORA:** Thank you for the clarification. I
14 appreciate that.

15 **BY MS. CARFORA**

16 **Q.** Dr. Henry, did Dr. Thiessen document and show her work in
17 the analysis offered in her expert report consistent with the
18 1998 guidelines for neurotoxicity?

19 **A.** So, again, the guidelines are guidelines. They tell you
20 the things that you should, in fact, include. And strengths
21 and limitations and uncertainties, and all of those long lists
22 of great things we like to have, are included in those lists.
23 And, no, I did not find those elements to be present.

24 **Q.** Dr. Henry, in your opinion, did Dr. Thiessen cite or apply
25 the principles and practices from the 1998 guidelines?

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1 A. The generalized, like, steps of the guidelines were there.
2 But, again, it was a little bit intermingled in some areas with
3 the TSCA Section 5. So I found that to be unclear and
4 confusing.

5 Q. And, Dr. Henry, do you know if -- did Dr. Thiessen cite or
6 apply any of the principles and procedures based on the
7 Guidance for Interested Persons under TSCA?

8 A. I don't recall that guidance being cited.

9 Q. And do you recall whether Dr. Thiessen cited to the
10 application of systematic review for TSCA?

11 A. I don't believe she did.

12 Q. And do you recall whether those guidelines were available
13 to her at the time she submitted her expert report in this
14 case?

15 A. The -- the Guidance for Interested Parties, again, was
16 mandated to be published in June of 2017. So, certainly, that
17 was available.

18 The application of systematic review in TSCA risk
19 evaluations was published, I believe, it was May of 2018. So
20 about a year before these reports started to come to us.

21 Q. Do you recall any discussion in the guidance for
22 interested -- Guidance for Interested Persons in how an
23 interested person, submitting a draft risk evaluation to EPA,
24 might go about having that draft risk evaluation peer reviewed?

25 A. I don't recall that specific element. It definitely

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1 outlined the various methods and approaches and the things that
2 need be included to be considered equivalent to TSCA. I don't
3 recall the public comment.

4 But, certainly, if we received one, since EPA is the
5 entity -- or in this case the judge -- is to make a risk
6 determination, and we must subject a draft for risk evaluation
7 to a public comment period.

8 So I -- I just don't recall if there is a specific section
9 on that, but that would be my expectation.

10 **Q.** Dr. Henry, would it help refresh your recollection if I
11 showed you the Guidance to Interested Persons?

12 **A.** Yes, it would.

13 **MS. CARFORA:** Your Honor, this is an exhibit that is
14 in evidence. May I have permission to show the witness Trial
15 Exhibit 538?

16 **THE COURT:** All right. No objection?

17 **MR. CONNETT:** No objections, Your Honor.

18 **THE COURT:** Go ahead.

19 **MS. CARFORA:** Mr. Hambrick, Trial Exhibit 538,
20 Page 11, and the middle of the page there just before Section
21 3.2.

22 Mr. Hambrick, can you also do the paragraph above that as
23 well?

24 (Document displayed.)
25

HENRY - EXAMINATION / CARFORA

1 BY MS. CARFORA

2 Q. Dr. Henry, have you had a chance to read this?

3 A. Yes.

4 MS. CARFORA: Can you clear the screen, Mr. Hambrick?

5 (Document removed from display)

6 BY MS. CARFORA

7 Q. Dr. Henry, does that refresh your recollection as to how
8 an interested party could have their draft risk evaluations
9 peer reviewed?

10 A. Yes. It says that we do not expect them to have them peer
11 reviewed prior to submission; that if we took up their data
12 analysis and evaluations, that it would become part of the EPA
13 document that would get peer reviewed then. Because peer
14 review is, again, required under TSCA for a draft risk
15 evaluation.

16 Q. Dr. Henry, can you explain for the Court the concept of
17 fit for purpose as it's included in the draft risk evaluation
18 rule?

19 A. Well, again, fit for purpose can mean many different
20 things. I mean, it's easier to say in an example, but
21 essentially for the purpose we still have to get to the same
22 risk evaluation -- risk determination decision point.

23 But if the data and the methods that you have available --
24 this goes back to a basic principle risk assessment that you
25 do -- sometimes it's an iterative process. If you have, you

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1 know, data and information available that uses that
2 sophisticated methods, you rely on those and not keep refining
3 if you're comfortable regarding the uncertainties and the
4 conclusions.

5 But as things get more complicated or if -- especially for
6 something you're going to rely on for regulation, the bar is
7 much higher; that you need to make sure the data is all the
8 things I talked about earlier.

9 So it just depends on the data. We -- we -- for example,
10 in our risk evaluation exposure scenarios or exposure pathways
11 may be conducted at a higher level of detail and complexity
12 than others.

13 **BY MS. CARFORA**

14 **Q.** Thank you.

15 Dr. Henry, I just want to clarify. Is it your testimony
16 that the NRC 2006 was an unreliable source of information for
17 understanding exposure to fluoride?

18 **MR. CONNETT:** Misstates testimony, and leading.

19 **THE COURT:** Sustained. Rephrase the question.

20 **BY MS. CARFORA**

21 **Q.** Dr. Henry, can you clarify for the Court your criticism of
22 Dr. Thiessen's reliance on the NRC 2006 report for exposure
23 data?

24 **A.** It was not so much a criticism on the relying on that, but
25 that it was -- it's been quite a few years since then and

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1 that to ensure or meet the best available, that there should at
2 least have been an attempt to look for newer information. If
3 it didn't exist, it didn't exist. You could have, you know,
4 argued that was the best.

5 But there was nothing in the original reports to indicate
6 that any attempt was made to find up-to-date best available
7 information.

8 Q. Dr. Henry, is causation relevant to a hazard
9 identification?

10 A. It's definitely a consideration. The neurotox guidelines
11 do talk about that. The more you can try to establish that,
12 the better. It adds confidence to your hazard assessment.

13 Q. And so can you clarify, was it your position in this
14 litigation that plaintiffs had to prove causation?

15 A. No.

16 Q. And is your -- does the basis of your opinion in any way
17 rest on whether plaintiffs proved causation?

18 MR. CONNETT: Leading.

19 THE COURT: Overruled.

20 (Brief pause.)

21 BY MS. CARFORA

22 Q. And you also mentioned in your direct -- in your cross
23 testimony that your critiques were based on methodology
24 approaches. Can you just clarify that very quickly?

25 A. My critiques were based on several different types of

HENRY - EXAMINATION / CARFORA

1 limitations in the methods that were applied and/or
2 documentation or justifying how they were applied or why they
3 were applied. So assumptions weren't necessarily always
4 explained.

5 Justification for selection of studies, for example,
6 usually is based on a quality assessment, and I didn't see that
7 kind of thing in there.

8 Q. And can you explain why that's important here? Isn't that
9 just form over substance?

10 A. No. I mean, this gets to that determination of best
11 available science, and that is which is reliable, which means
12 you need to do a quality evaluation, and unbiased.

13 So again, you know, Dr. Thiessen or Dr. Grandjean may have
14 thought those were the best studies, but without providing an
15 external reader, such as myself, an analysis to show that they
16 evaluated against some sort of criteria or such, how would I be
17 convinced?

18 Again, I -- earlier I said I'm a person with a lot of
19 questions, so I want to know. And this is just the -- this
20 kind of, you know, demonstration that the best available
21 science was determined by some method, and then used in a risk
22 evaluation to get to that risk determination, is -- it's what
23 our stakeholders demand.

24 Q. And who are your stakeholders?

25 A. Well, we have had a lot of scrutiny from Congress around

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1 TSCA lately. So Congress certainly.

2 Stakeholders from the non-governmental organizations are
3 also quite vocal. Industry is a stakeholder obviously. And,
4 again, we're federal civil servants, so the American public.

5 Again I mentioned, I think I mentioned, but every time we
6 go to public comment and peer review, we get lots and lots of
7 input. I mean I think, I hope, it's partly because we're
8 putting together a new program, but I would say that what they
9 mostly demand is more documentation and more justification. So
10 this is why we're using the methods we do to demonstrate that
11 the TSCA requirements are being met.

12 Q. And, Dr. Henry, if a database includes human data -- I'm
13 sorry. Yes. If a database includes human data, does that mean
14 we should just ignore the animal data?

15 A. Not necessarily. Again, you have to do this data
16 evaluation for quality and weight of evidence. So you might --
17 there are risk assessments that only use human data. Typically
18 it's a lot more than two cohorts, but there is also those that
19 include both. And then there are those that include only
20 animal data.

21 Q. Now, you spoke a little bit about uncertainty factors.
22 And I'd like to know, Dr. Henry, are uncertainty factors
23 applied generally to a database or are they applied to
24 individual studies?

25 A. To individual studies.

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1 Q. And how does OPPT go about determining uncertainty
2 factors?

3 A. So the generalized process here is to go through this data
4 gathering, data evaluation, looking at the data. You want to
5 look at the highest quality data. And then you have to
6 essentially take each study and under -- and go through the
7 process of the four uncertainty factors and whether or not they
8 need be applied or based on that study and what exposure
9 scenario it's going to be applied to.

10 Q. And, Dr. Henry, did -- did EPA actually make a finding of
11 unreasonable risk in the draft NMP risk evaluation?

12 A. It's a draft, so it is not the final agency conclusion,
13 because it is a draft. We develop a draft and then because
14 TSCA says that a risk determination is part of the risk
15 evaluation, and a draft risk evaluation needs to be peer
16 reviewed, so that whole package, the draft risk evaluation goes
17 out for a public comment and peer review. So at this time, at
18 this day, that is not a final determination. It's a draft.

19 Q. And is it just the final determination that goes out for
20 peer review or is it everything in the draft that gets peer
21 reviewed?

22 A. Everything. Mostly the peer review is a scientific peer
23 review, and so it -- it is -- the scientific peer review is
24 limited to a risk assessment part, but that doesn't mean that
25 people don't opine on the other part.

HENRY - EXAMINATION / CARFORA

1 Q. So is it -- so is it true that both the final
2 determination and all of the methodologies and approaches used
3 in that determination could change after peer review?

4 MR. CONNETT: Leading.

5 A. Yes. So if, for example, peer reviewers identify another
6 piece of data that we somehow missed, or if they recommend, for
7 example, a different modeling approach, or what often happens
8 at these peer reviews is a lot of deliberation around
9 particular studies and around uncertainty factors.

10 So things can change after peer review, all the way from
11 the data used to support the final risk evaluation, all the way
12 through the dose response modeling could change. The study we
13 used could change. Any number of things could change.
14 Exposure could change. And so then, therefore, the risk could
15 change.

16 Q. Dr. Henry, are you familiar with the Bradford Hill
17 criteria?

18 A. Yes.

19 Q. And are the Bradford Hill criteria considerations in the
20 OPPT application of systematic review document?

21 MR. CONNETT: Your Honor, at this point we're beyond
22 the scope.

23 THE COURT: I believe so. There was no discussion of
24 that in the cross.

25 MS. CARFORA: There was discussion of causation, Your

HENRY - RECROSS / CONNETT

1 Honor. This goes directly to causation.

2 **THE COURT:** Well, maybe make a proffer. How does
3 this relate to causation?

4 **MS. CARFORA:** Well, the testimony in this trial to
5 date has been that the Bradford Hill criteria are the -- nine
6 criteria that are considered in determine -- in weighing
7 association as it relates to causation.

8 **MR. CONNETT:** The question -- the issue on cross,
9 Your Honor, was just whether causation is required. And so,
10 you know, I think that's where the scope would be proper.

11 **THE COURT:** All right. That's correct. It was
12 about, at least an implicit assertion by the plaintiffs that
13 Dr. Henry applied a causation analysis when that is not
14 required under TSCA. It didn't get into whether or not the
15 causation analysis itself was substantively correct.

16 Beyond the scope.

17 (Brief pause.)

18 **MS. CARFORA:** I have no further questions, Your
19 Honor.

20 **THE COURT:** All right. Anything further on recross?

21 **MR. CONNETT:** One question, Your Honor.

22 **RECROSS-EXAMINATION**

23 **BY MR. CONNETT**

24 **Q.** Dr. Henry, of the 69 pages in Dr. Thiessen's expert
25 report, how many of those pages discuss Section 5?

1 **A.** Without actually pulling up the report and counting, I
2 could not say.

3 But her margin of exposure analysis speaks to it quite
4 heavily as the front methodology, and then also in the tables
5 of the MOES there's reference to MOEs typically derived for
6 those types. And then she cites to four or six different PMN
7 risk determinations -- PMNs being new chemical
8 determinations -- in several places.

9 **Q.** Okay. Dr. Henry, is it more -- sorry, strike that.

10 Was it more or less than five pages of the 69 page report
11 where Dr. Thiessen discussed Section 5?

12 **MS. CARFORA:** Objection, Your Honor. I think this is
13 unfair to the witness, and I think he's asked it --

14 **THE COURT:** Hold on. If she can remember. But,
15 frankly, this question is not helpful to the Court. If you
16 want to spend your time on this question, you can do it, but
17 it's not helpful to me.

18 **MR. CONNETT:** Okay --

19 **A.** As I recall --

20 **MR. CONNETT:** Your Honor, I will withdraw the
21 question.

22 **THE COURT:** All right. Conclude?

23 **MR. CONNETT:** Yes. Yes, Your Honor.

24 **THE COURT:** Anything further on redirect?

25 **MS. CARFORA:** No, Your Honor. Thank you.

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1 **THE COURT:** All right. Dr. Henry, thank you for your
2 testimony. You will be excused. Appreciate your time.

3 **THE WITNESS:** Thank you, Your Honor.
4 (Witness excused.)

5 **THE COURT:** All right. So next witness.

6 **MS. CARFORA:** EPA calls Joyce Donohue.
7 Mr. Hambrick, if we can get that six-minute deposition
8 video up, that would be great.

9 **THE COURT:** Okay.

10 JOYCE DONOHUE,
11 called as a witness for the Defendant herein,
12 testified via videotaped deposition played in open court.)

13 (Time noted: 4:43 p.m. to 4:50 p.m.)

14 **THE COURT:** All right. Anything further in that
15 regard?

16 **MS. CARFORA:** No. I would -- nothing further with
17 Dr. Donohue.

18 I would inquire to the Court, I was under the impression
19 the schedule was until 4:30 Pacific time today. We only
20 have -- we have about 15 minutes of deposition testimony that
21 we wanted to read into the record; but other than that, I
22 believe we'll probably rest.

23 **THE COURT:** Actually, I think we said until 5:30.
24 Right, Angie?

25 **THE CLERK:** Yes, Your Honor.

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1 **THE COURT:** So if you want to take the next 15
2 minutes to read that testimony, this is the time to do it.

3 **MS. CARFORA:** Thank you.

4 **MR. DO:** Your Honor, if we could just have a time
5 check.

6 **THE COURT:** What's that?

7 **MR. DO:** Could we get a time check so that -- we want
8 to make sure we reserve time for any possible rebuttal
9 witnesses.

10 **THE COURT:** Okay. Angie, what are we showing on the
11 clock?

12 **THE CLERK:** Your Honor, plaintiff has 32 minutes and
13 30 seconds remaining.

14 Defendant has 44 minutes and 1 second remaining. That
15 does not include the deposition testimony that was just
16 presented, the 6 minutes.

17 **MR. DO:** Much appreciated.

18 Your Honor, if we could inquire whether or not there will
19 be any rebuttal witnesses that will be helpful in terms of
20 gauging whether or not we --

21 **THE COURT:** Mr. Connett, are you planning a rebuttal
22 witness tomorrow?

23 **MR. CONNETT:** Your Honor, we are still considering
24 that. I can say that if we have rebuttal, it will be very
25 short.

PROCEEDINGS

1 **THE COURT:** Okay.

2 **MR. DO:** In that case, I think we can go ahead and
3 spend just be about 10, 15 minutes of the Court's time now.

4 **THE COURT:** All right.

5 **MR. DO:** By deposition designations we will be
6 calling now Audrey Adams on behalf of her son Kyle Adams.

7 **THE COURT:** Okay.

8 **MR. DO:** And if the Court will allow, I and Ms. Bhat
9 will be doing the questions and answering of that.

10 **THE COURT:** All right. That sounds good.

11 Sorry, Ms. Carfora.

12 **MR. CONNETT:** Your Honor, could I just clarify --
13 sorry.

14 I wanted to clarify one thing, Your Honor, just so it's
15 clear. And that is that plaintiffs have designated from these
16 depositions, but we are electing not to read it -- read it out
17 loud. We have it in the Appendix C.

18 **THE COURT:** Okay. How much of that is in the
19 appendix?

20 **MR. CONNETT:** All of our designations are in the
21 appendix, Your Honor.

22 **THE COURT:** Was there a stipulation?

23 **MR. CONNETT:** Yes. We have the stipulation that
24 everything in Appendix C is in evidence.

25 **THE COURT:** Okay.

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1 **MR. DO:** Yes, Your Honor, that stipulation is still
2 pending.

3 And in light of the fact that plaintiffs may be calling a
4 rebuttal witness, I think we'll forego reading this into the
5 record. However, if there is time tomorrow, if the Court will
6 permit calling witnesses out of order, we may renew our request
7 to do so.

8 **THE COURT:** What you're proposing to do is to read
9 excerpts from deposition excerpts that have already been
10 admitted; is that right?

11 **MR. DO:** Yes, Your Honor. As you may recall, you
12 (audio interference) for the sake of emphasis, for the parties
13 to read into the record if desired.

14 **THE COURT:** So that's up to you whether you want it
15 emphasized or not. Up to you. You know, I don't know how much
16 time you want to use on closings and stuff. I mean, that's --

17 **MR. DO:** If you don't mind, Your Honor, we would like
18 to make that decision after the possible rebuttal testimony of
19 tomorrow, if you don't mind.

20 **THE COURT:** All right. Any objection?

21 **MR. CONNETT:** No, Your Honor.

22 **THE COURT:** All right. So, and that will conclude
23 your case then; right? The only thing left are these excerpts?

24 **MR. DO:** That's right Your Honor.

25 **THE COURT:** And the cross of the rebuttal.

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1 **MR. DO:** That's correct, Your Honor.

2 **THE COURT:** All right. At most, it will be one short
3 witness for rebuttal tomorrow; correct?

4 **MR. CONNETT:** I believe so, Your Honor. But if we
5 had more than one witness, it was -- it's going to be very
6 short, if we have anything. I don't know yet if we are.

7 **THE COURT:** Okay. Well, you are constrained by your
8 own clock there.

9 **MR. CONNETT:** Very much so.

10 **THE COURT:** That is the beauty of this process.
11 So I leave the judgment to you, but you should count on
12 making your closings tomorrow, and we'll resume at 8:30.

13 **MR. CONNETT:** Your Honor --

14 **MR. DO:** Your Honor, one more housekeeping matter.
15 So we have been doing disclosures to each side on a daily
16 basis with regards to who the witnesses will be and also, of
17 course, any exhibits that will be shown, et cetera.

18 Could we get assurances from Mr. Connett with regards to,
19 again, the identity and, also, subject matter of the rebuttal
20 so that we can prepare accordingly.

21 **THE COURT:** That's fair. You should do that within
22 the next hour.

23 **MR. CONNETT:** Well, Your Honor, also two points of
24 clarification.

25 One is for closing, would we have the option of, say,

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1 using our first 25 minutes or so for our -- for closing and
2 then reserving the remainder for a rebuttal?

3 **THE COURT:** Yeah. No, you can do a rebuttal.

4 **MR. CONNETT:** And the other question, Your Honor,
5 that we had is: Do you intend -- do you envision us filing,
6 like, post trial briefing for findings of fact, things that
7 sort.

8 **THE COURT:** I'm going to talk about that tomorrow, I
9 think, after I hear your closings. But I am inclined to
10 explore several things with you all, and one of those would be
11 revised proposed findings of fact and conclusions of law in
12 view of the evidence.

13 In particular, it would be helpful to have cites, rather
14 than having my staff and I try to hunt through every transcript
15 and every document.

16 So you should be prepared to talk about that. I won't be
17 charging it to you in terms of where we go from here. That
18 will be my time.

19 I do want to take some time to talk about where we go from
20 here, and I also want to explore all the possible alternatives
21 here. All right?

22 **MR. CONNETT:** Thank you, Your Honor.

23 **MR. DO:** Thank you, Your Honor.

24 **THE COURT:** Okay. So we'll see you 8:30 tomorrow
25 morning.

PROCEEDINGS

1 **MR. CONNETT:** Thank you.

2 **MR. DO:** Thank you.

3 **THE CLERK:** Court is adjourned.

4 (Whereupon at 4:57 p.m. further proceedings
5 were adjourned until Wednesday, June 17, 2019
6 at 8:30 a.m.)

I N D E X

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VIDEOTAPED TESTIMONY

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CERTIFICATE OF REPORTER

I certify that the foregoing is a correct transcript from
the record of proceedings in the above-entitled matter.

Debra L. Pas

Debra L. Pas, CSR 11916, CRR, RMR, RPR

Tuesday, June 16, 2020